Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Ackerman, 2007	RCT	U.S. Number of centers and clinic setting not reported	Radicular pain in S1 dermatomal distribution; L5-S1 disk herniation confirmed by MRI; electromyographic evidence of S1 nerve root involvement; pain intensity >7; duration not specified	Pregnancy; allergies to steroids; steroid use within 3 weeks prior to study; bleeding history; infection; use of anticoagulants; allergies to study medications	Approached: 487 Eligible: 285 Randomized: 90 (30 vs. 30 vs. 30) Analyzed: 90 at 24 weeks	A: Transforaminal epidural injection with 40 mg triamcinolone (1 ml) and saline (4 ml), with fluoroscopic guidance (n=30) B: Interlaminar epidural injection with 40 mg triamcinolone (1 ml) and saline (4 ml), with fluoroscopic guidance (n=30) C: Caudal epidural injection with 40 mg triamcinolone (1 ml) and saline (19 ml), with fluoroscopic guidance (n=30)
Ahadian, 2011	RCT	U.S. Two centers	≥18 years of age; distal radicular pain ≥6 months in duration; previously benefitted from transforaminal epidural steroid injection with betamethasone 6 to 12 mg with recurrence of pain; VAS score ≥50 out of 100	Pregnancy; infection; coagulopathy; uncontrolled diabetes or hypertension; allergy to iodinated contrast medium; interventional therapies for pain in last 90 days	Approached: 449 Eligible: 98 Randomized: 98 (32 vs. 33. vs. 33) Analyzed: 98 at 12 weeks	A: Transforaminal epidural injection with 12 mg dexamethasone (3 ml), with fluoroscopic guidance (n=32) B: Transforaminal epidural injection with 8 mg dexamethasone (2 ml), with fluoroscopic guidance (n=33) C: Transforaminal epidural injection with 4 mg dexamethasone (1 ml), with fluoroscopic guidance (n=33)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Ackerman, 2007	A vs. B vs. C: Age (mean): 34 vs. 39 vs. 36 years Male: 67% vs. 70% vs. 63% Duration of symptoms (days): 35 vs. 33 vs. 38 Baseline pain (0 to 10): 8.6 vs. 8.8 vs. 8.9 Baseline ODI (0-70): 30 vs. 33 vs. 37	A vs. B vs. C: Treatments prior to intervention: Not specified Treatments following intervention: Tizanidine and celecoxib; otherwise not specified Other patient characteristics: Not reported	Number and frequency of injections: 3 injections performed at 2 week intervals Number of levels: Transforaminal vs. interlaminar vs. caudal Provider experience: Not reported	Fluoroscopic guidance with contrast verification	Head-to-head comparison of different approaches for epidural injections
Ahadian, 2011	A vs. B vs. C: Age (median): 58 vs. 57 vs. 60 years Male: 53% vs. 70% vs. 88% Duration of symptoms >2 years: 91% vs. 88% vs. 91% Baseline pain (0 to 100): 73 vs. 71 vs. 68 Baseline ODI (0 to 50): 23 vs. 24 vs. 24	A vs. B vs. C: Treatments prior to intervention: Previous response to transforaminal epidural injection with betamethasone Treatment following intervention: Not specified L3-L4 disc abnormality: 25% vs. 45% vs. 36% L4-L5 disc abnormality: 31% vs. 39% vs. 27% Central stenosis: 28% vs. 39% vs. 39% Post laminectomy syndrome: 9.4% vs. 15% vs. 3.0%	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification in epidural space	Transforaminal epidural injection with different doses of corticosteroid

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Ackerman, 2007	A vs B vs C: <u>Pain</u> Complete pain relief (complete, partial, or no pain relief): 30% (9/30) vs. 10% (3/30) vs. 3% (1/30) at 24 weeks: A vs. B, RR 3.0 (95% CI 0.90 to 10.07); A vs. C, RR 9.0 (95% CI 1.21 to 66.71); B vs. C, RR 3.0 (95% CI 0.33 to 27.23) Complete or partial pain relief: 83% (25/30) vs. 60% (18/30) vs. 57% (17/30) at 24 weeks: A vs B, RR 1.39 (95% CI 1.0 to 1.9); A vs. C, RR 1.47 (95% CI 1.03 to 2.10; B vs. C, RR 1.06 (95% CI 0.69 to 1.62) Pain (mean, 0-10): 2.4 vs. 5.7 vs. 6.1 at 2 weeks after last injection ($p<0.05$ for A vs. B or C) <u>Function</u> ODI (mean, 0-70): 14 vs. 13 vs. 14 at 2 weeks after last injection ($p>0.05$) <u>Other outcomes</u> Beck Depression Inventory (mean, 0-63): 12 vs. 11 vs. 13 at 2 weeks after last injection ($p>0.05$)
Ahadian, 2011	A vs. B vs. C: <u>Pain</u> Pain (mean, 0-100 VAS, estimated from graph): 73 vs. 71 vs. 68 at baseline; 42 vs. 38 vs. 41 at 4 weeks; 51 vs. 37 vs. 50 at 8 weeks; 52 vs. 45 vs. 54 at 12 weeks ($p>0.05$ for between group differences at all time points) <u>Function</u> ODI (mean, 0-100 VAS, estimated from graph): 23 vs. 24 vs. 24 at baseline; 18 vs. 17 vs. 18 at 4 weeks; 20 vs. 17 vs. 19 at 8 weeks; 21 vs. 19 vs. 20 at 12 weeks, ($p>0.05$ for between group differences at all time points) <u>Global improvement</u> Global impression of change <=3 (7 point scale): No difference between groups, data not reported Global satisfaction scale >=2 (5 point scale): No difference between groups, data not reported

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Ackerman, 2007	24 weeks	A vs. B vs. C: 0% (0/90)	Appears complete	A vs. B vs. C: No infection, headache, intravascular injection, reaction to contrast material, steroid, or subarachnoid injection in any patient	Not reported	Fair
Ahadian, 2011	12 weeks	A vs. B vs. C: 0% (0/98)	Appears complete	A vs. B vs. C: Paresthesia: 6% (6/98) overall No serious adverse events	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Arden, 2005 Price, 2005	RCT	UK Multicenter Specialty clinics	18 to 70 years of age; back pain with unilateral radicular symptoms, extending below the knee, with signs including reduced SLR and a positive sciatic nerve stretch test; duration 4 weeks to 18 months; normal laboratory results; lumbar spine X-ray to exclude other causes of radicular pain including infection and malignancy	Previous back surgery; bleeding disorder or anticoagulation; bilateral symptoms; previous epidural injection; current litigation relating to sciatica; significant psychological disorder	Approached: Not reported Eligible: Not reported Randomized: 228 (120 vs. 108) Analyzed: 228 (120 vs. 108) at 12 months, including 25 (14 vs. 11) with missing data	A: Interlaminar epidural injection with 80 mg triamcinolone acetonide plus 0.125% bupivacaine (10 ml) (n=120) B: Soft tissue injection into interspinous ligament of normal saline (2 ml) (n=108)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Arden, 2005 Price, 2005	A vs. B: Age (mean): 43 vs. 44 years Male: 52% vs. 54% Duration of symptoms: Mean not reported (4 weeks to 18 months by inclusion criteria); 38% vs. 35% acute (4 weeks to 4 months) Baseline leg pain (0-100 VAS): 52 vs. 56 Baseline back pain (0-100 VAS): 40 vs. 44 Baseline ODI (0-100): 44 vs. 45	A vs. B: Treatments prior to intervention: Physiotherapy package with education and exercise regimens Treatments following intervention: Not specified HAD depression: 7 vs. 4 Off work with sciatica: 34% vs. 32% Decreased sensation: 78% vs. 63% Absence/decreased ankle reflexes: 32% vs. 32% Decreased power: 42% vs. 43%	Number and frequency of injections: Mean not reported, up to three injections at 3 week intervals if ODI improved less than 75% from baseline Number of levels: Not reported Provider experience: "Operators were all very experienced"	None reported	Soft tissue injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Arden, 2005 Price, 2005	A vs. B: <u>Pain</u> Leg pain (mean improvement from baseline, 0-100 VAS): 12 vs. 10 at 3 weeks; 15 vs. 15 at 6 weeks; 13 vs. 18 at 12 weeks; 17 vs. 20 at 52 weeks (p>0.05 at all time points) Leg pain improved >50%: 35% (42/120) vs. 26% (28/108) at 3 weeks, RR 1.35 (95% CI 0.90 to 2.02); 47% (56/120) vs. 41% (44/108) at 6 weeks, RR 1.15 (95% CI 0.85 to 1.54); 43% (52/120) vs. 46% (50/108) at 12 weeks, RR 0.94 (95% CI 0.70 to 1.25); 48% (58/120) vs. 44% (48/108) at 52 weeks, RR 1.09 (95% CI 0.82 vs 1.44) Back pain (mean improvement from baseline, 0-100 VAS): 6 vs. 2 at 3 weeks; 6 vs. 8 at 6 weeks; 4 vs. 7 at 12 weeks, 8 vs. 9 at 52 weeks <u>Function</u> ODI (mean improvement from baseline, 0-100): 10 vs. 7 at 3 weeks; 13 vs. 10 at 6 weeks; 12 vs. 12 at 12 weeks;16 vs. 14 at 52 weeks (p>0.05 at all time points) (p>0.05 at all time points) ODI (0-100, estimated from figure): 44 vs. 45 at baseline; 32 vs. 39 at 3 weeks (p=0.05); 31 vs. 35 at 6 weeks (p=0.15); 33 vs. 34 at 12 weeks (p=0.92), 29 vs. 33 at 52 weeks (p=0.55) ODI improved >75%: 12% (15/120) vs. 3.7% (4/108) at 3 weeks, RR 3.38 (95% CI 1.16 to 9.86); 15% (18/120) vs. 13% (14/108) at 6 weeks, RR 1.16 (95% CI 0.61 to 2.21); 16% (19/120) vs 22% (24/108) at 12 weeks, RR 0.71 ((5% CI 0.41 to 1.23); 32% (38/120) vs. 30% (32/108) at 52 weeks, RR 1.07 (95% CI 0.72 to 1.58) SF-36: No statistically significant differences (data not reported) <u>Other outcomes</u> Surgery: 13% (15/120) vs. 13% (14/108) through 52 weeks, RR, 0.96 (95% CI 0.49 to 1.9) Physiotherapy: 26% vs. 23% over 52 weeks Other injections: 13% vs. 11% over 52 weeks HAD anxiety (mean improvement from baseline): 2 vs. 2 at 3 weeks; 2 vs. 2 at 6 weeks; 2 vs. 3 at 12 weeks; 3 vs. 3 at 52 weeks HAD depression (mean improvement from baseline): 1 vs. 1 at 3 weeks; 2 vs. 2 at 6 weeks; 2 vs. 2 at 12 weeks; 2 vs. 2 at 52 weeks Analgesic use (mean change in number consumed in a week, baseline 37 vs. 48): -6 vs. -11 at 3 weeks; -8 vs. -13 at 6 weeks; -9 vs. -16 at 12 weeks; -14 vs. -16 at 52 weeks Days off work with sciatica (median change, baseline 98 vs. 93): -21 vs -21 at 3 weeks; -21 vs. -21 at 6 weeks; -37 vs. -23 at 12 weeks; -65 vs. -33 at 52 weeks

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Arden, 2005 Price, 2005	12 months	A vs. B: 12% (14/120) vs. 10% (11/108)	Appears complete	A vs. B: One post-dural puncture headache Non-specific headache: 3% (4) vs. 4% (4)	UK National Health Service, Health Technology Assessment Programme	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Aronsohn, 2010	RCT	U.S. Number of settings and clinic setting not reported	Chronic lumbar discogenic pain; radiculopathy; MRI or CT scans consistent with diagnosis of contained disc herniation at L3-4, L4-5, or L5S-1; ≥50% preserved disc height; duration not specified	Not Reported	Approached: Not reported Eligible: Not reported Randomized: 50 (24 vs. 26) Analyzed: Unclear	A: Epidural injection (approach not reported) with 40 mg methylprednisolone plus 0.25% bupivacaine (3 ml), with fluoroscopic guidance (n=24) B: Lumbar discectomy using Stryker disc Dekompressor (n=26)
Becker, 2007	RCT	Germany Single center Orthopedic surgery	Unilateral lumbar radicular compression, confirmed by MRI or CT showing herniation of nucleus pulposus or scarring after previous surgery; duration ≥6 weeks; pain intensity moderate to severe	Need for early surgery; additional neurologic illnesses; cervical myopathy; systemic bone or joint illness; previous epidural or epidural perineural injection in the last 3 months; cortisone or opioid use in the last 6 months	Approached: Not reported Eligible: Not reported Randomized: 84 (25 vs. 27 vs. 32) Analyzed: 83 (24 vs. 27 vs. 32) at 24 weeks	A: Perineural epidural injection using oblique interlaminar approach with 10 mg triamcinolone plus unspecified local anesthetic (1 ml), with fluoroscopic guidance (n=24) B: Perineural epidural injection using oblique interlaminar approach with 5 mg triamcinolone plus unspecified local anesthetic (1 ml), with fluoroscopic guidance (n=24) C: Perineural epidural injection using oblique interlaminar approach with autologous conditioned serum (1 ml), with fluoroscopic guidance (n=24)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Aronsohn, 2010	A vs. B: Age (mean): 51 vs. 41 years Male: 56% vs. 64% Duration of symptoms: Not reported Baseline back pain (0-10): 7.1 vs. 7.5 Baseline radicular pain (0-10): 9.3 vs. 9.1 Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not reported Treatments following intervention: Not reported Other patient characteristics: Not reported	Number of injections: Single injection Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance	Percutaneous microdiscectomy
Becker, 2007	A vs. B vs. C: Age (mean): 54 years (reports no difference between groups) Male: Reports no difference between groups, data not provided Duration of symptoms: Reports no difference between groups, data not provided Baseline pain: Not reported Baseline function: Not reported	A vs. B vs. C: Treatments prior to intervention: Pain medication discontinued for 2 weeks prior to first injection Treatments following intervention: No additional medical therapy or physical therapy	Number and frequency of injections: 3 injections at 1 week intervals Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance	Perineural epidural injection with different doses of corticosteroid or autologous conditioned serum

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Aronsohn, 2010	A vs. B: Pain Back pain (0-10 VAS): 7.1 vs. 7.5 at baseline; 6.7 vs. 3.0 at 1 week (p<0.05); 6.5 vs. 1.0 at 6 weeks (p<0.05) Radicular pain (0-10 VAS): 9.3 vs. 9.1 at baseline; 4.8 vs. 8.0 at 1 week (p<0.05); 2.0 vs. 7.1 at 6 weeks (p<0.05)
Becker, 2007	A vs. B vs. C: Pain Pain (mean, 0-100 VAS, estimated from graph): 84 vs. 82 vs. 78 at baseline; 30 vs. 29 vs. 35 at 4 weeks; 30 vs. 27 vs. 17 at 6 weeks; 22 vs. 33 vs. 22 at 22 weeks; mean difference A vs. B: -4.2 (95% CI -19 to 11); A vs. C: 9.3 (95% CI -4.9 to 24); for B vs. C: 14 (95% CI -0.4 to 27) Function ODI (mean, 0-50): 19 vs. 21 vs. 22 at baseline; 11 vs. 12 vs. 14 at 6 weeks; 11 vs. 12 vs. 11 at 10 weeks; 11 vs. 11 vs. 12 at 22 weeks (p>0.05 at all time points)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Aronsohn, 2010	6 weeks	Not reported	Appears complete	A vs. B: Paresthesia: 4.2% (1/24) vs. 13% (3/26) Infection: 0% vs. 3.8% (1/26)	Not reported	Poor
Becker, 2007	22 weeks	Not reported	Appears complete	A vs. B vs. C: Severe headache: 4.0% (1/25) vs. 3.7% (1/27) vs. 3.1% (1/32) "No serious adverse events"	No funding received	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Beliveau, 1971	RCT	UK Single center Rheumatology clinic	Moderate or severe unilateral sciatica thought to be caused by a herniated disk, with or without neurologic signs; duration of symptoms and imaging findings not specified	Not reported	Approached: Not reported Eligible: Not reported Randomized: 48 (24 vs. 24) Analyzed: Unclear at 1 week	A: Caudal epidural injection with 80 mg methylprednisolone (2 ml) + 0.5% procaine (40 ml) (n=24) B: Caudal epidural injection with 0.5% procaine (42 ml) (n=24)
Breivik, 1976	RCT	Norway Single center Neurology and anesthesiology clinic	Incapacitating chronic (several months to several years) low back pain and sciatica unresponsive to non-invasive treatments; radiculography with metrizamide showing arachnoiditis, prolapsed disc, no abnormality, or inconclusive findings	Not reported	Approached: Not reported Eligible: Not reported Randomized: 35 (16 vs. 19) Analyzed: 35	A: Caudal epidural injection with 80 mg methylprednisolone and 0.25% cc bupivacaine (20 ml) (n=16) B: Caudal epidural injection with 0.25% bupivacaine (20 ml) followed by 100 cc saline (n=19)
Buchner, 2000	RCT	Germany Single center Orthopedic clinic	Herniated disk ≥5 mm confirmed by MRI with corresponding clinical symptoms of nerve root compression; positive straight leg raise test at <60 degrees; age <50 years; duration not specified	Previous lumbar surgery; lumbar spinal stenosis by MRI; cauda equina syndrome; acute severe motor paresis	Approached: Not reported Eligible: Not reported Randomized: 36 (17 vs. 19) Analyzed: 36 at 6 months	A: Interlaminar epidural injection with 100 mg methylprednisolone in 0.25% bupivacaine (10 ml) (n=17) B: No epidural injection (n=19)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Beliveau, 1971	A vs. B: Age (mean): 41 years (overall) Male: 75% Duration of symptoms: Not reported Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Not reported	Not reported	Interlaminar epidural injection with local anesthetic
Breivik, 1976	A vs. B: Age (mean): Not reported, range 30-63 years Male: 50% vs. 47% Duration of symptoms: Not reported Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Prior surgery: 25% vs. 37% Other patient characteristics: Not reported	Number and frequency of injections: Mean 2.6 vs. 2.5 injections; repeated at weekly intervals for up to 3 injections; 5/16 vs. 11/19 patients received other type of injection after no relief from 3 injections Number of levels: Not reported Provider experience: Not reported	Not reported	Caudal epidural local anesthetic injection
Buchner, 2000	A vs. B: Age (mean): 37 vs. 32 years Male: 47% vs. 79% Duration of symptoms (weeks): median 8 vs. 8 Baseline pain (0-100): 84 vs. 81 Hannover Functional Ability Questionnaire: 39% vs. 40%	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Bed rest; analgesics; NSAIDS or tramadol; graded rehabilitation including hydrotherapy, electroanalgesia, spinal mobilization physiotherapy	Number and frequency of injections: 3 injections within 14 days Number of levels: Single level Provider experience: Not reported	Not reported	No injection

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Beliveau, 1971	A vs. B: <u>Pain</u> Improved or completely relieved (clinician rated): 75% (18/24) vs. 67% (16/24), RR 1.13 (95% CI 0.78 to 1.62)
Breivik, 1976	A vs. B: <u>Pain</u> Pain relief "considerable" (defined as diminution of pain and/or paresis to enable return to work or rehabilitation for other work): 65% (9/16) vs. 26% (5/19) RR, 2.14 (95% CI 0.90 to 5.09)
Buchner, 2000	A vs. B: <u>Pain</u> Pain (0-100 VAS): 84 vs. 81 at baseline; 31 vs. 37 at 2 weeks; 33 vs. 38 at 6 weeks; 33 vs. 39 at 6 months (p>0.05 at all time points) <u>Function</u> Hannover Functional Ability Questionnaire: 39% vs. 40% at baseline; 64% vs. 57% at 2 weeks; 62% vs. 58% at 6 weeks; 62% vs. 57% at 6 months (p>0.05 at all time points) <u>Other outcomes</u> Return to work: 88% (15/17) vs. 74% (14/19) at 6 months, RR: 1.20 (95% CI 0.87 to 1.65) Overall results "very good" or "good": 88% (15/17) vs. 74% (14/19), RR 1.20 (95% CI 0.87 to 1.65) at 6 months Surgery: 12% (2/17) vs. 21% (4/19) at 6 months, RR 0.56 (95% CI 0.12 to 2.68)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Beliveau, 1971	1 week	Not reported	Appears complete	A vs. B: Mild headache and dizziness for <30 minutes in 10 patients (not reported by group) Procedure stopped in 2 patients due to theca penetration	Not reported	Poor
Breivik, 1976	Unclear	Not reported	Appears complete (5/16 vs. 11/19 received other injection per protocol after 3 failed primary injections)	Not reported	Upjohn	Poor
Buchner, 2000	6 months	None	Appears complete	Not reported	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Burgher, 2011	RCT	US Single center Pain clinic	≥18 years of age, intervertebral disc herniation with low back and leg pain due to encroachment of disc material on a spinal nerve root as confirmed by CT or MRI; positive nerve root tension sign with unilateral symptoms at a single level of the lumbosacral spine; duration ≤3 months	Pain intensity was less than 3 of 10 or more than 8 of 10 if already taking opioids; recent spinal trauma; cauda equina syndrome; progressive motor deficit; chronic anticoagulation; infectious etiology; workers' compensation claim; history of adverse reaction to study medications; 1 or more corticosteroid injection in the preceding 4 months; pregnant; severe medical disease	Approached: 33 Eligible: Not reported Randomized: 26 (15 vs. 11) Analyzed: 23 (14 vs. 9)	A: Transforaminal epidural injection with 40 or 80 mg triamcinolone (2 ml) plus 2% lidocaine (1 ml), with fluoroscopic guidance (n=15) B: Transforaminal epidural injection with 200 or 400 mcg clonidine (2 ml) plus 2% lidocaine (1 ml), with fluoroscopic guidance (n = 11)
Bush, 1991	RCT	UK Single center Rheumatology clinic	Unilateral sciatica associated with paresthesia; positive straight leg raise, duration >1 month; imaging findings not required	Cauda equina syndrome; nonorganic physical signs; other serious pathology; inadequate contraception in women of child-bearing age	Approached: Not reported Eligible: Not reported Randomized: 28 Analyzed: 23 (12 vs. 11)	A: Caudal epidural injection with 80 mg triamcinolone acetonide in normal saline with 0.5% procaine hydrochloride (total 25 ml) (n=12) B: Caudal epidural injection with saline (25 ml) (n=11)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Burgher, 2011	A vs. B: Age (mean): 50 vs. 44 years Male: 67% vs. 82% Duration of symptoms (weeks): 5.3 vs. 5.0 Baseline pain (0-10 NRS): 7.0 vs. 7.0 Baseline ODI (0-50): 29 vs. 31	A vs. B: Treatments prior to intervention: 67% vs. 91% opioids Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Mean 2.3 vs. 2.0 injections, repeated at 10-14 day intervals Number of levels: 1 Provider experience: Not reported	Fluoroscopic guidance (digital subtraction angiography) with contrast verification	Transforaminal epidural injection with clonidine and local anesthetic
Bush, 1991	A vs. B: Age (mean): 38 vs. 37 years Male: 83% vs. 45% Duration of symptoms: Not reported Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 2 at 2 week intervals Number of levels: Caudal injection Provider experience: Not reported	None reported	Caudal epidural injection with normal saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Burgher, 2011	A vs. B: <u>Pain</u> Pain, difference between groups compared with baseline (0-10 NRS): at 2 weeks, 0.11 (95% CI -1.79 to 2.01); at 4 weeks, 1.54 (95% CI -0.52 to 3.60) <u>Function</u> Roland Morris Disability Questionnaire, difference between groups compared with baseline: at 2 weeks, 2.96 (95% CI -1.04 to 6.96); at 4 weeks, 5.67 (95% CI 1.22 to 10.1) ODI, difference between groups compared with baseline: at 2 weeks, 5.86 (95% CI -0.57 to 12.3); at 4 weeks, 7.04 (95% CI 0.83 to 13.2) Multidimensional Pain Inventory, difference between groups compared with baseline: at 2 weeks, -4.83 (95% CI -0.57 to 12.3); at 4 weeks, -0.35 (95% CI -6.96 to 6.26) <u>Global Assessment</u> Patient Global Impression of Change <=2 (much improved) at 4 weeks: 50% vs. 67% (p=0.669) <u>Other outcomes</u> Surgery: 6.7% (1/15) vs. 27% (3/11) at 6 months, 0.24 (95% CI) 0.30 to 2.05
Bush, 1991	A vs. B: <u>Pain</u> Pain (0-100 VAS): at 4 weeks 16 vs. 45 (p not reported); at 1 year 14 vs. 30 (p>0.05) <u>Function</u> Function/lifestyle (6-18 scale): at 4 weeks 16 vs. 14 (p not reported); at 1 year 17 vs. 16 (p>0.05) <u>Other outcomes</u> Surgery: 8.3% (1/12) vs.18% (2/11), RR 0.39 (95% CI 0.04 to 3.80)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Burgher, 2011	4 weeks for pain, function, and global impression of change; 6 months for surgery	A vs. B: 6.7% (1/15) vs. 18% (2/11)	Appears complete	A vs. B: Discomfort at injection site: 27% (4/15) vs. 18% (2/11) Worsening of symptoms: 13% (2/15) vs. 36% (4/11) Lightheadedness: 7% (1/15) vs. 45% (5/11) Drowsiness: 20% (3/20) vs. 18% (2/11) Dry mouth: 20% (3/20) vs. 18% (2/11) Weakness: 7% (1/15) vs. 36% (4/11) Constipation: 7% (1/15) vs. 18% (2/11) Nausea: 13% (2/15) vs. 9% (1/11) 1 group B patient withdrew due to side effects (nausea, lightheadedness)	National Institutes of Health	Fair
Bush, 1991	1 year	A vs. B: 18% (5/28)	Appears complete	A vs. B: Irregular menses: 8% (1/12) vs. 0%	ER Squibb & Sons and the Boots Company PLC	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Buttermann, 2004	RCT	USA Single center Surgery clinic	18 to 70 years of age; lumbar disc herniation >25% of cross-sectional area of the spinal canal on MRI or CT; failure to respond to 6 weeks of noninvasive treatments; duration not specified	Cauda equina syndrome; pars defect at the level of the herniation; far-lateral disc herniation; multilevel symptomatic disc herniation; recurrent disc herniation	Approached: 169 Eligible: Not reported Randomized: 100 (50 vs. 50) Analyzed: 71 (23 vs. 48) at 2-3 years (on-treatment analysis)	A: Interlaminar epidural injection with 10 to 15 mg betamethasone, with fluoroscopic guidance in 76% of patients (n=50) B: Discectomy (technique not specified) (n=50)
Candido, 2013	RCT	US Single center Pain management center	>18 years of age, unilateral lumbosacral radiculopathic pain, MRI findings of degenerative lumbar disc disease including protruding or bulging discs, desiccated discs, or herniated discs with preservation of at least 50% of disc height	Required injections for multi-level disease; a history of previous spinal surgery; lumbar epidural steroid injection(s) in the past year; allergies to study medications, using systemic corticosteroids or chronic opioid use	Approached: Not reported Eligible:137 Randomized:106 (53 vs. 53) Analyzed: 100 (50 vs. 50)	A. Lateral parasagittal interlaminar epidural injection with 120 mg methylprednisolone acetate (2 ml) plus lidocaine 1% (1 ml), with fluoroscopic guidance B. Midline interlaminar epidural injection with 120 mg methylprednisolone acetate (2 ml) plus lidocaine 1% (1 ml), with fluoroscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Buttermann, 2004	A vs. B: Age (mean): 41 vs. 40 years Male: Not reported Duration of symptoms (months): 3.3 vs. 3.8 Baseline back pain (0-10): 5.4 vs. 5.2 Baseline leg pain (0-10): 7.4 vs. 7.0 Baseline ODI (0-100): 47 vs. 48	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient Characteristics: Smokers: 30% vs. 36% Size of disc herniation: 42% vs. 43% Motor deficit: 82% vs. 88%	Number and frequency of injections: Mean not reported, patients could receive 1-3 at one week intervals based on response Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance in 76% of patients undergoing epidural injection	Epidural steroid injection vs. discectomies vs. crossover
Candido, 2013	A vs. B: Age (mean): 49 v. 49 years Male: 48% vs. 40% (p=0.5) Duration of symptoms: 14 vs. 14 months Baseline pain at rest (mean, 0-10 NRS): 4.9 vs. 5.1 Baseline pain during movement (mean, 0-10 NRS): 7.6 vs. 7.2 Baseline function (mean ODI, 0 to 100): 44.9% vs. 40.6% (p=NS)	A vs. B: Treatments prior to intervention: Pain medications: 54% vs. 64%; Opioid use: 28% vs. 36%; NSAIDS: 54% vs. 62% (p>0.05) Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of intervention: mean number of injections 1.82 vs. 1.88 (p>0.05) Number of levels: Appears to be single Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space	Head-to-head comparison of alternative epidural steroid injection methods

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Buttermann, 2004	A vs. B: Pain Back pain (mean, 0-10 VAS, estimated from graph): 5.4 vs. 5.2 at baseline, 3.0 vs. 2.0 at 1-3 months; 2.6 vs. 1.7 at 4-6 months; 2.3 vs. 1.8 at 7-12 months; 2.4 vs. 1.9 at 1-2 years; 1.8 vs. 2.4 at 2-3 years (p>0.05 at all time points) Leg pain (mean, 0-10 VAS, estimated from graph): 7.4 vs. 7.0 at baseline; 4.1 vs. 1.4 at 1-3 months; 2.7 vs. 1.2 at 4-6 months; 1.8 vs. 1.1 at 7-12 months; 1.7 vs. 1.2 at 1-2 years; 0.8 vs. 1.5 at 2- 3 years (p>0.05 at all time points) Function ODI (0-100): 47 vs. 48 at baseline; 34 vs. 22 at 1-3 months; 15 vs. 16 at 4-6 months; 14 vs. 14 at 7-12 months; 11 vs. 14 at 1-2 years; 8 vs. 16 at 2-3 years (p>0.05 at all time points except 1-3 months) Motor deficit (estimated from graph): 82% (41/50) vs. 88% (44/50) at baseline, RR, 0.93 (95% CI 0.79 to 1.10); 72% (36/50) vs. 38% (19/50) at 1-3 months, RR 1.89 (95% CI 1.28 to 2.81); 30% (8/27) vs. 20% (10/50) at 4-6 months, RR 1.48 (95% CI 0.66 to 3.31); 20% (5/25) vs. 12% (6/50) at 7-12 months, RR 1.67 (95%CI 0.56 to 4.93); 12% (3/24) vs. 8.0% (4/50) at 1-2 years, RR 1.56 (95% CI 0.38 to 6.43); 8.7% (2/23) vs. 4.0% (2/50) at 2-3 years, RR 2.17 (95% CI 0.33 to 14.5) Other outcomes Medication use "much less" (5 category scale, much less to much more): 16% (8/50) vs. 24% (12/50) at 1-3 months, RR 0.43 (95 % CI 0.23 to 0.78); 57% (13/23) vs. 32% (15/47) at 2-3 years, RR 1.77 (95 % CI 1.02 to 3.07)
Candido, 2013	A vs. B Pain Pain, Numeric Rating Scale at rest (NRS, 11-point scale, estimated from graph): at baseline, 4.9 vs. 5.1; at 14 days, 2.8 vs. 3; at 28 days, 2.7 vs. 3; at 60 days, 2.6 vs. 3.2; at 120 days, 2.6 vs. 3; at 180 days, 2 vs. 3.2; at 365 days, 2 vs. 3.2 (p>0.05) Pain, Numeric Rating Scale during movement (NRS, 11-point scale, estimated from graph): at baseline, 7.6 vs. 7.2; at 14 days, 3.3 vs. 4.5; at 28 days, 3.3 vs. 4.5; at 60 days, 3.7 vs. 5; at 120 days, 3.7 vs. 4.7; at 180 days, 3.7 vs. 5; at 365 days, 4 vs. 5 (p>0.05) Function ODI (scores 0-50 multiplied by 2 and presented as a percentage from 0-100%, estimated from graph): at baseline: 44.9% vs. 40.6% (p=NS); at 14 days, 25% vs. 28%; at 28 days, 23% vs. 27%; at 60 days, 22% vs. 25%; at 120 days, 24% vs. 27%; at 180 days, 21% vs. 31%; at 365 days, 20% vs. 33% (p>0.05) Other Outcomes Patient Satisfaction (5-point scale, where 1 = complete dissatisfaction and 5 = complete satisfaction, estimated from GRA ph): at 1 day, 3.9 vs. 3.6; at 14 days, 4.1 vs. 2.9; at 28 days, 3.7 vs. 3.4; at 60 days, 3.7 vs. 3. 4; at 120 days, 3.5 vs. 3.3; at 180 days, 4 vs. 3.2; at 365 days, 4.1 vs. 3.2 (p-values not reported, but states "better satisfaction" in group A on days 7, 14, 180, and 365.)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Buttermann, 2004	2-3 years	A vs. B: 3% (3/100) at 3 years	46% (23/50) of patients in epidural injection group crossed over to discectomy at 2-3 years	A vs. B: Epidural injection (n=50): 2 incidental dural puncture, 3 recurrent disc herniation Discectomy (n=77, including crossovers): 2 incidental durotomies, 1 seroma	None	Poor
Candido, 2013	12 months	A vs. B 3 vs. 3	Appears complete	Discomfort and pain at the injection site: 22% vs. 30% (p>0.05) Headache, nonpositional, not related to dural puncture: 22% vs. 12% (p>0.05) Nausea: 6% vs. 14% (p>0.05)	Department of Anesthesiology, Advocate Illinois Masonic Medical Center, Chicago, IL	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Candido, 2008	RCT	US Single center Clinical setting unclear	Low back pain; unilateral lumbosacral radiculopathy	Previous spinal surgery; epidural steroid injections in the past year; allergy to study drugs; concurrent systemic steroids; opioid use; pregnancy	Approached: Not reported Eligible: Not reported Randomized: 60 (30 vs. 30) Analyzed: 57 (29 vs. 28) at 6 months	A: Posterolateral interlaminar epidural injection with 80 mg methylprednisolone plus lidocaine 1% (1 ml), with fluoroscopic guidance B: Transforaminal epidural injection with 80 mg methylprednisolone plus lidocaine 1% (1 ml), with fluoroscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Candido, 2008	A vs. B: Age (mean): 52 vs. 52 years Male: 57% vs. 40% Duration of symptoms <3 months: 24% vs. 7.1% Baseline pain (0-10 VAS): 6.8 vs. 6.3 Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of intervention: Appears to be single Number of levels: Appears to be single Provider experience: Attending physicians supervising fellows	Fluoroscopy with contrast verification in epidural space	Head-to-head comparison of alternative epidural steroid injection methods

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Candido, 2008	A vs. B: <u>Pain</u> Pain intensity (mean, 0-100 VAS): 63 vs. 63 at baseline; 41 vs. 49 at 2 weeks (p=0.31); 52 vs. 53 at 1 month (p=0.94); 47 vs. 43 at 3 months (p=0.68); 41 vs. 47 at 6 months (p=0.46)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Candido, 2008	6 months	None reported	2 in transforaminal injection group and 1 in parasagittal interlaminar group did not receive treatment and were excluded	A vs. B: 1 parasagittal interlaminar group had paresthesia requiring procedure to be aborted (excluded from analysis)	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Carette, 1997	RCT	Canada Two centers Type of clinic not reported	>18 years of age; sciatica for >4 weeks and <1 year with constant or intermittent pain in one or both legs radiating below knee; nerve root irritation based on positive straight leg raise and/or motor, sensory, or reflex deficits, with CT evidence of herniated disk corresponding to clinical findings; ODI >20	Cauda equina syndrome; CT findings of nerve root compression from causes other than herniated disk; epidural steroid injection in the preceding year; prior low back surgery; pregnant; known blood-coagulation disorder or allergy to local anesthetics	Approached: Not reported Eligible: Not reported Randomized: 158 (78 vs. 80) Analyzed: 156 (77 vs. 79) at 3 months	A: Interlaminar epidural injection with 80 mg methylprednisolone (2 ml) plus isotonic saline (8 ml) (n=78) B: Interlaminar epidural injection with isotonic saline (1 ml) (n=80)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Carette, 1997	A vs. B: Age (mean): 39 vs. 41 years Male: 72% vs. 59% Duration of symptoms (weeks): 12.9 vs. 13.0 Baseline pain (0 to 100): 66 vs. 62 Baseline ODI (0 to 100): 50 vs. 50	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Acetaminophen, otherwise not specified Other patient characteristics: Disability compensation: 24% vs. 21% First episode of sciatica: 76% vs. 76% L4-L5: 49% vs. 51% L5-S1: 45% vs. 48%	Number and frequency of injections: Mean 2.1 injections, repeated injections permitted at 3 and 6 weeks for failure to improve Number of levels: Single level Provider experience: Not reported	None reported	Interlaminar epidural injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Carette, 1997	A vs. B: *(differences are difference in change from baseline; ANCOVA results adjusted for male sex and living partner performed but reported as similar to unadjusted and not presented)* <u>Pain</u> Pain (0-100 VAS): 66 vs. 62 at baseline;45 vs. 49 at 3 weeks, difference -8.6 (95% CI -18 to 0.3); 39 vs. 40 at 3 months, difference -4.0 (95% CI -15 to 7.2) McGill Present Pain Intensity (0-5): 2.6 vs. 2.8 at baseline; 2.2 vs. 2.4 at 3 weeks, difference 0.0 (95% CI -0.4 to 0.4); 1.9 vs. 1.9 at 3 months, difference 0.2 (95% CI -0.3 to 0.7) McGill Pain-rating Index (0-77): 28 vs. 26 at baseline; 20 vs. 22 at 3 weeks; difference -3.4 (95% CI -8.1 to 1.3), 18 vs. 18 at 3 months, difference -1.2 (95% CI -7.2 to 4.9) <u>Function</u> ODI (0-100): 50 vs. 50 at baseline, 42 vs. 44 at 3 weeks, difference -2.5 (95% CI -7.1 to 2.2); 32 vs. 35 at 3 months, difference -1.9 (95% CI -9.3 to 5.4) ODI <=20: 20% (15/77) vs. 16% (13/80) at 3 weeks, RR 1.20 (95% CI 0.61 to 2.35); 38% (29/77) vs. 42% (33/79) at 3 months, RR 0.90 (95% CI 0.61 to 1.33) Marked or very marked improvement: 33% (25/76) vs. 30% (23/78) at 3 weeks, RR 1.12 (95% CI 0.70 to 1.78); 55% (41/74) vs. 56% (43/77) at 3 months, RR 0.99 (95% CI 0.75 to 1.32) Sickness Impact Profile, Overall (0 to 100): 22 vs. 21 at baseline; 16 vs. 18 at 3 weeks; difference -2.5 (95% CI -5.1 to 0.1); 12 vs. 13 at 3 months, difference -1.2 (95% CI -5.2 to 2.8) (no differences on physical or psychosocial dimensions subscales) Restricted activity in previous 2 weeks (number of days): 9.9 vs. 9.7 at baseline; 8.9 vs. 7.9 at 3 weeks; difference 0.8 (95% CI -0.6 to 2.2); 5.9 vs. 5.4 at 3 months; difference 0.3 (95% CI -1.8 to 2.5) <u>Other outcomes</u> Underwent surgery: 26% (n=77) vs. 25% (n=79) at 12 months (p=0.90, log-rank test) Returned to work within 3 months: 33% (14/43) vs. 44% (18/41), RR 0.74 (95% CI 0.43 to 1.29) Lack of efficacy withdrawal: 15% (12/78) vs. 25% (20/80) at 3 months, RR 0.62 (95% CI 0.32 to 1.17)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Carette, 1997	3 months	A vs. B: 1.3% (1/78) vs. 1.2% (1/80)	Appears complete	A vs. B: Dural puncture: 1.3% (1/78) vs. 1.2% (1/80) Transient headache: 27% (21/78) vs. 20% (16/80) (p=0.30)	Medical Research Council of Canada and the Canadian Arthritis Society	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Cocelli, 2009	RCT	Turkey Single center Clinic setting unclear	20-55 years of age; acute discal radiculopathy <3 months duration not responding to conservative management; radiologic disc bulge corresponding to symptoms; ODI score >20	Bilateral symptoms; neurological deficits; prior lumbar disc surgery; severe medical comorbidities; urinary retention; allergy to study drugs	Approached: Not reported Eligible: Not reported Randomized: 70 (40 vs. 30) Analyzed: 70 at 6 months	A: Interlaminar epidural injection with 10 mg betamethasone diproprionate and 4 mg betamethasone sodium phosphate plus 0.125% bupivacaine (total 20 ml) (n=40) B: Interlaminar epidural injection with 80 mg triamcinolone acetonide plus 0.125% bupivacaine (total 20 ml) (n=40)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Cocelli, 2009	A vs. B: Age (mean): 49 vs. 50 years Male: 25% vs. 40% Duration of symptoms (weeks): 3 vs. 3 Baseline pain (0-10 VAS): 9.5 vs. 9.3 Baseline ODI (0-100): 51 vs. 62	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Amitriptyline 10 mg starting on day of injection to 50 mg/day for 6 months and postural exercise program L3-L4: 20% vs. 20% L4-L5: 55% vs. 60% L5-S1: 20% vs. 20%	Not reported	None reported	Head-to-head comparison of alternative corticosteroids

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Cocelli, 2009	A vs. B: <u>Pain</u> Pain (0-10 VAS): 9.5 vs. 9.3 at baseline, 5.7 vs. 1.1 at 2 weeks; 0.8 vs. 0.0 at 6 weeks; 0.0 vs. 0.0 at 3 months; 0.0 vs. 0.0 at 6 months <u>Function</u> ODI (0-100): 51 vs. 62 at baseline, 36 vs. 32 at 2 weeks; 25 vs. 23 at 6 weeks; 22 vs. 22 at 3 months; 19 vs. 20 at 6 months

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Cocelli, 2009	6 months	Reports none	Appears complete	A vs. B: "No side effects related to this treatment in any of the patients"	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Cohen, 2012	RCT	US and Germany Multicenter Pain clinics	18 to 70 years of age; lumbosacral radiculopathy for 4 weeks to 6 months; leg pain as or more severe than back pain; failure of conservative therapy; MRI evidence of pathologic disc condition correlating with symptoms	Coagulopathy; systemic infection; unstable medical or psychiatric condition; previous spinal surgery; previous epidural steroid injection; allergy to contrast dye	Approached: 164 Eligible: 96 Randomized: 84 (28 vs. 26 vs. 30) Analyzed: 84 at 1 month (primary analysis)	A. Transforaminal epidural injection with 60 mg methylprednisolone acetate in 2 ml sterile water and 0.5% bupivacaine (0.5 ml), with fluoroscopic guidance (n=28) B. Transforaminal epidural injection with 4 mg etanercept in 2 ml sterile water and 0.5% bupivacaine (0.5 ml), with fluoroscopic guidance (n=26) C. Transforaminal epidural injection with 2 ml sterile water and 0.5% bupivacaine (0.5 ml) , with fluoroscopic guidance (n=30)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Cohen, 2012	A vs. B vs. C: Age (mean): 43 vs. 41 vs. 41 years Male: 79% vs. 69% vs. 63% Duration of symptoms (months): 2.61 vs. 2.67 vs. 2.82 Baseline leg pain (0-10): 5.71 vs. 6.62 vs. 6.31 Baseline back pain (0-10): 5.30 vs. 6.08 vs. 4.75 Baseline ODI (0-100): 42.93 vs. 41.12 vs. 40.87	A vs. B vs. C: Treatments prior to intervention: Not reported Treatments following intervention: Analgesic medications Other patient characteristics: Disability/worker's compensation/medical board: 4 % vs. 12% vs. 10% Baseline opioid therapy: 39% vs. 39% vs. 47% L4-5: 29% vs. 35% vs. 27% L5-S1: 43% vs. 50% vs. 47%	Number and frequency of injections: 86% vs. 88% vs. 93% received 2 injections (2nd injection two weeks after first) Number of levels: 1-2 levels, dose divided for multiple levels Provider experience: Board-certified pain medicine physician or attending or pain-management fellow at teaching hospital	Fluoroscopic guidance with contrast verification of nerve root and epidural space	Transforaminal epidural injection with etanercept and local anesthetic Transforaminal epidural injection with saline and local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Cohen, 2012	A vs. B vs. C: *(difference ANCOVA adjusted for study site, sex, duration of pain, opioid use, baseline outcome score)* <u>Pain</u> Leg Pain (0-10 NRS): 5.71 vs. 6.62 vs. 6.31 at baseline; 2.54 vs. 3.56 vs. 3.78 at 1 month, difference -1.26 (95% CI -2.79 to 0.27) for A vs. C, -1.01 (95% CI -2.60 to 0.58) for A vs. B Back pain (0-10 NRS): 5.30 vs. 6.08 vs. 4.75 at baseline, 3.49 vs. 4.41 vs. 4.01 at 1 month, difference -0.52 (95% CI -1.85 to 0.81) for A vs. C, -0.92 (95% CI -2.28 to 0.44) for A vs. B <u>Function</u> ODI (0-100): 42.9 vs. 41.1 vs. 40.9 at baseline, 24.1 vs. 40.3 vs. 30.0 at 1 month, difference -5.87 (95% CI -15.6 to 3.85) for A vs. C, -16.2 (95% CI -26.0 to -6.27) for A vs. B <u>Global Assessment</u> Global Perceived Effect positive (pain improved and patient satisfied): at 1 month: 82% (23/28) vs. 58% (15/26) vs. 57% (17/30) (p=0.14); A vs. B adjusted OR 3.16 (95% CI 0.88 to 11.3), A vs. C adjusted OR 3.12 (95% CI 0.91 to 10.8), B vs. C adjusted OR 0.99 (95% CI 0.33 to 2.94); 65% vs. 50% vs. 48% at 3 months, 63% vs. 45% vs. 48% at 6 months Success (>=50% decrease in leg pain and positive Global Perceived Effect): at 1 month 75% (21/28) vs. 42% (11/26) vs. 50% (15/30), A vs. C adjusted OR 3.63 (95% CI 1.10 to 12.0), A vs. B adjusted OR 2.62 (95% CI 0.82 to 8.37), B vs. C adjusted OR 0.72 (95% CI 0.24 to 2.16); at 3 months 50% (14/28) vs. 42% (11/26) vs. 43% (13/30); at 6 months 29% (8/28) vs. 38% (10/26) vs. 40% (12/30), A vs. B RR 0.74 (95% CI 0.35 to 1.59), A vs. C RR 0.71 (95% CI 0.34 to 1.48), B vs. C RR 0.96 (95 % CI 0.50 to 1.85) <u>Other outcomes</u> Surgery: at 12 months 21% (6/28) vs. 23% (6/26) vs. 17% (5/30); A vs. B RR 0.93 (95% CI 0.34 to 2.52), A vs. C RR 1.29 (95% CI 0.44 to 3.74), B vs. C RR 1.38 (95% CI 0.48 to 4.01) Remained on active duty: at 12 months 100% (15/15) vs. 93% (13/14) vs. 90% (17/19); A vs. B: RR 1.04 (95% CI 0.61 to 1.77); A vs. C: RR 1.06 (95% CI 0.64 to 1.74); B vs. C: RR 1.06 (95% CI 0.64 to 1.74) Analgesic use decreased >=20%: 63% (17/28) vs. 36% (9/30) vs. 50% (14/30) at 1 month (p=0.24), A vs. B adjusted OR 3.0 (95% CI 0.83 to 10.8), A vs. C adjusted OR 1.67 (95% CI 0.48 to 5.77), B vs. C adjusted OR 0.56 (95% CI 0.16 to 1.89); 92% (11/12) vs. 65% (7/11) vs. 75% (9/12) at 6 months, A vs. B RR 1.44 (95% CI 0.89 to 2.32), A vs. C RR 1.22 (95% CI 0.85 to 1.76), B vs. C RR 0.84 (95% CI 0.49 to 1.47)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Cohen, 2012	6 months; surgery and remained on active duty assessed through 1 year	None	Appears complete	A vs. B. vs. C: Worsening pain: 4% (1/28) vs. 19% (5/26) vs. 20% (6/30) New neurological symptom: 0% (1/28) vs. 4% (1/26) vs. 3% (1/30) Nonlocal infection: 0% (0/28) vs. 4% (1/26) vs. 10% (3/30) Nonlocal rash: 4% (1/28) vs. 0% vs. 0%	John P. Murtha Neuroscience and Pain Institute, International Spinal Intervention Society, the Center for Rehabilitation Sciences Research	Good

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Cohen, 2012b	RCT	USA Multicenter Pain clinics	Age >18 years; signs and symptoms of lumbosacral radiculopathy; leg pain as great as or greater than back pain; agreement to receive injection regardless of MRI findings	Previous back surgery; duration of pain >4 years; treated with epidural steroid injection within the past 2 years; serious neurologic deficit; serious psychiatric disease	Approached: 323 Eligible: Unclear Randomized: 132 (67 vs. 65) Analyzed: 132	A: Transforaminal epidural injection with 60 mg methylprednisolone, 0.25% bupivacaine (1 ml), and saline (0.5 ml) (total 3 ml) or interlaminar epidural injection with 60 mg methylprednisolone, 0.25% bupivacaine (1 ml), and saline (1.5 ml) (total 4 ml), with fluoroscopic guidance; treatment and level based on MRI findings (n=67) B: Injection as above, based on history and physical examination findings (n=65)
Cuckler, 1985	RCT	USA >1 center Type of clinics not reported	Acute unilateral sciatica and well defined, discrete neurological findings or neurogenic claudication; failed to improved with at least two weeks of non-invasive therapy; duration of symptoms not specified; imaging findings not required	Lumbar surgery for similar symptoms or any lumbar surgery within 6 months	Approached: Not reported Eligible: Not reported Randomized: 73 (42 vs. 31) Analyzed: 73 at 20-22 months	A: Interlaminar epidural injection with 80 mg methylprednisolone (2 ml) and 1% procaine (5 ml) (n=42) B: Interlaminar epidural injection with saline (2 ml) and 1% procaine (5 ml) (n=31)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Cohen, 2012b	A vs. B: Age (mean): 51 vs. 53 Male: 42% vs. 45% Duration of symptoms (years): 1.5 vs. 1.6 Baseline leg pain (0-10 NRS): 6.6 vs. 6.7 Baseline back pain (0-10 NRS): 6.1 vs. 6.1 Baseline ODI (0-100): 44 vs. 45	A vs. B: Treatments prior to intervention: Not specified Treatments following interventions: Not specified Opioid use: 37% vs. 31%	Number and frequency of injections: Could undergo second injection after 1 month, 66% vs. 77% underwent two injections Number of levels: Appears single; 61% vs. 77% received transforaminal and 31% vs. 23% interlaminar injections Provider experience: Not reported	Fluoroscopic guidance with contrast verification in epidural space	Epidural steroid injection based on MRI findings vs. without MRI
Cuckler, 1985	A vs. B: Age (years): 49 vs. 50 Male: 48% vs. 55% Duration of symptoms (months): 17.3 vs. 13.8 Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Previous surgery: 2% (1/42) vs. 7% (2/31) Herniated disc: 52% vs. 45% Spinal stenosis: 48% vs. 55%	Number of injections: 43% (18/42) vs. 58% (18/31) received second injection with corticosteroid and local anesthetic after 24 hours due to no relief after initial injection Number of levels: Single level Provider experience: Not reported	None reported	Epidural injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Cohen, 2012b	A vs. B: <u>Pain</u> Leg pain (0-10 NRS): 6.6 vs. 6.7 at baseline, 3.6 vs. 4.4 at 1 month (p=0.12), 2.7 vs. 3.0 at 3 months (p=0.77) Back pain (0-10 NRS): 6.1 vs. 6.1 at baseline, 4.0 vs. 4.6 at 1 m (p=0.21), 3.2 vs. 3.5 at 3 m (p=0.81) <u>Function</u> ODI (0-100): 44 vs. 45 at baseline, 35 vs. 35 at 1 month (p=0.98), 30 vs. 31 at 3 months (p=0.79) Medication reduction: 48% (26/67) vs. 27% (14/65) at 1 month (p=0.02); 57% (17/67) vs. 56% (14/65) at 3 months (p=0.96) <u>Global assessment</u> Global Perceived Effect positive: 69% (42/67) vs. 55% (36/65) at 1 month (p=0.12), 53% (26/67) vs. 40% (24/65) at 3 months (p=0.17) Overall success (>=2 point decrease in leg pain plus positive Global Perceived Effect): 41% (24/67) vs. 35% (23/65) at 3 months (p=0.54) No statistically significant effect of age, sex, type of injection, duration of pain, opioid use, baseline ODI, or baseline pain on likelihood of success
Cuckler, 1985	A vs. B: <u>Pain</u> Pain improved >=75%: 26% (11/42) vs. 13% (4/31) at mean 20 months, RR 2.40 (95% CI 0.93 to 6.58) Pain improved >=75%, herniated disc patients: 26% (6/23) vs. 15% (2/13) at mean 20 months, RR 1.94 (95% CI 0.56 to 7.66) <u>Other outcomes</u> Surgery: 38% (16/42) vs. 29% (9/31) at mean 20 months, RR 1.50 (95% CI 0.86 to 2.81) Surgery (herniated disk): 43% (10/23) vs. 23% (3/13) at mean 20 months, RR 2.56 (95% CI 1.12 to 7.35)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Cohen, 2012b	3 months	A vs. B: 1.5% (2/132) lost to followup (states 5 patients who did not undergo epidural injections excluded from analysis, but 132 of 132 randomized patients presented in results)	Appears complete	A vs. B: 3 patients had worsening of pain, 1 had unstable angina, and 1 had arrhythmia following epidural steroid injection (group not specified)	John P. Murtha Neuroscience and Pain Institute, International Spinal Intervention Society, the Center for Rehabilitation Sciences Research	Fair
Cuckler, 1985	13 to 30 months (mean 20.2 vs. 21.5 months)	None	Appears complete	Not reported	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Dashfield, 2005	RCT	UK Single center Pain clinic	>18 years of age; sciatica accompanied by neurosensory and motor deficits, with or without back pain; duration 6 to 18 months; imaging findings not required	Previous spinal surgery; coagulopathy; progressive motor neuron disorders; peripheral vascular disease; epidural corticosteroid injection within three months	Approached: Not reported Eligible: Not reported Randomized: 60 (30 vs. 30) Analyzed: 52 (29 vs. 23) at 6 months	A: Caudal epidural injection with triamcinolone 40 mg plus 1% lidocaine (10 ml), with fluoroscopic guidance (n=33) B: Epidural injection with 40 mg triamcinolone plus 1% lidocaine (10 ml) and saline (50 to 150 ml), via sacral approach with spinal endoscopic guidance (n=27)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Dashfield, 2005	A vs. B: Age (mean): 48 vs. 45 years Male: 51% vs. 37% Duration of symptoms (months): 9.4 vs. 10.1 Baseline pain (0 -10): 6.6 vs. 7.2 Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number of injections: Single injection Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification in epidural space for caudal epidural injection, Spinal endoscopic guidance	Epidural injection with steroid, with spinal endoscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Dashfield, 2005	A vs. B: <u>Pain</u> Pain (mean, 0-10): 6.6 vs. 7.2 at baseline; 5.7 vs. 6.7 at 6 weeks; 5.4 vs. 6.4 at 3 months; 5.2 vs. 6.0 at 6 months Short-form McGill Pain Questionnaire, sensory subscale (scale not reported): 14.8 vs. 15.5 at baseline; 13.9 vs. 16.0 at 6 weeks; 13.1 vs. 16.4 at 3 months; 12.5 vs. 16.0 at 6 months Short-form McGill Pain Questionnaire affective subscale (scale not reported): 4.2 vs. 5.9 at baseline; 4.7 vs. 4.9 at 6 weeks; 4.6 vs. 6.6 at 3 months; 4.2 vs. 5.9 at 6 months Present Pain Intensity (0-10): 2.8 vs. 3.5 at baseline; 2.3 vs. 2.6 at 6 weeks; 2.1 vs. 3.1 at 3 months; 2.0 vs. 2.5 at 6 months <u>Other outcomes</u> HAD-anxiety (0-21): 10.9 vs. 103 at baseline; 9.3 vs.10.0 at 6 weeks; 8.4 vs. 9.6 at 3 months; 7.8 vs. 8.7 at 6 months HAD-depression (0-21): 8.4 vs. 9.0 at baseline; 8.2 vs. 8.0 at 6 weeks; 7.7 vs. 8.0 at 3 months; 7.0 vs. 7.9 at 6 months

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Dashfield, 2005	6 months	A vs. B: 12% (4/33) vs. 15% (4/27) at 6 months	3 patients randomized to epiduroscopy crossed over to caudal injection and analyzed as treated	A vs. B: Post-procedural back discomfort: More frequent in spinal endoscopy group	Defense Secondary Care Agency	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Datta, 2011	RCT	India Single center Pain clinic	20-70 years of age; BMI 18-30 kg/m2; recurrent episodes of sciatica >4 weeks but <1 year with failure of ≥6 weeks conservative therapy; CT evidence of herniated disc at level correlating with symptoms and clinical findings; RDQ score >20	Requiring surgery, structural spinal deformities; symptoms from causes other than herniated disc; spinal injection in last year; prior low back surgery, chemonucleolysis or nucleotomy; pregnant; allergy to corticosteroids; use of tricyclic antidepressants or lithium	Approached: Not reported Eligible: Not reported Randomized: 207 (50 vs. 52 vs. 50 vs. 55) Analyzed: 163 (39 vs. 40 vs. 42 vs. 42) at 12 weeks	A: Caudal epidural injection with 80 mg methylprednisolone plus 0.125% bupivacaine (10-15 ml) (n=50) B: Caudal epidural injection with 80 mg triamcinolone plus 0.125% bupivacaine (10-15 ml) (n=52) C: Caudal epidural injection with 15 mg dexamethasone plus 0.125% bupivacaine (10-15 ml) (n=50) D: Caudal epidural injection with 0.125% bupivacaine (10-15 ml) (n=55)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Datta, 2011	A vs. B vs. C vs. D: Age (mean): 40 vs. 39 vs. 42 vs. 43 years Male: 92% vs. 94% vs. 90% vs. 91% Duration of leg pain (weeks): 16 vs. 17 vs. 16 vs. 16 Baseline pain (0-10 VAS): 7.5 vs. 7.4 vs. 7.3 vs. 7.2 Baseline RDQ (0-24): 21 vs. 22 vs. 21 vs. 22	A vs. B vs. C vs. D: Treatments prior to intervention: 51 vs. 49 vs. 47 vs. 48 diclofenac tablets/week Treatments following intervention: Analgesics other than diclofenac prohibited; no injections during followup Single disc: 82% vs. 86% vs. 88% vs. 86% Two or more discs: 18% vs. 14% vs. 12% vs. 14% L3-L4: 82% vs. 73% vs. 81% vs. 73% L4-L5: 78% vs. 75% vs. 80% vs. 64% L5-S1: 12% vs. 13% vs. 10% vs. 16%	Number and frequency of injections: Up to 3 injections over 1 year Number of levels: Caudal Provider experience: Not reported	None reported	Head-to-head comparison of various corticosteroids and epidural injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Datta, 2011	A vs. B vs. C vs. D: <u>Pain</u> Pain (0-10 VAS): 7.4 vs. 7.4 vs. 7.3 vs. 7.2 at baseline; 6.3 vs. 6.3 vs. 6.4 vs. 6.8 at 3 weeks; 4.9 vs. 4.8 vs. 5.2 vs. 6.2 at 12 weeks Complete pain relief (complete, incomplete but satisfactory, unsatisfactory): at 12 weeks: A vs. B: 43% (17/39) vs. (18/42), RR 1.45 (95% CI 0.86 to 2.60) A vs. C: 43% (17/39) vs. 38% (15/40), RR 1.16 (95% CI 0.68 to 1.99) A vs. D: 43% (17/39) vs. 26% (11/42), RR 1.66 (95% CI 0.89 to 3.10) <u>Function</u> RDQ improved >5 points (percent improvement, 0-24): at 3 weeks, 41% (16/39) vs. 40% (17/42) vs. 35% (14/40) vs. 38% (16/42): A vs. B: (16/39) vs. 40% (17/42), RR 1.66 (95% CI 0.60 to 1.71) A vs. C: 41% (16/39) vs. 35% (14/40), RR 1.17 (95% CI 0.67 to 2.06) A vs. D: (16/39) vs. 38% (16/42), RR 1.17 (95% CI 0.63 to 1.84) at 12 weeks: 69% (27/39) vs. 71% (30/42) vs. 62% (25/40) vs. 24% (10/42): A vs. B: 69% (27/39) vs. 71% (30/42), RR 0.97 (95% CI 0.73 to 1.29) A vs. C: 69% (27/39) vs. 62% (25/40), RR 1.11 (95% CI 0.81 to 1.52) A vs. D: 69% (27/39) vs. 24% (10/42): RR, 2.91(95% CI 1.63 to 5.19) <u>Other outcomes</u> Use of diclofenac (tablets/day): 3.8 vs. 3.3 vs. 4.0 vs. 4.8 at 3 weeks; 18 vs. 17 vs. 18 vs. 26 at 12 weeks Use of physiotherapy: 25% (9/39) vs. 17% (7/42) vs. 30% (12/40) vs 45% (19/42) at 6 weeks; 15% (6/39) vs. 12% (5/42) vs. 25% (10/40) vs. 38% (16/42) from 6 weeks to 3 months Sensory deficits: 13% (5/39) vs. 21% (9/42) vs. 28% (11/40) vs. 48% (20/42) at 3 months Underwent surgery: 6.0% (3/50) vs. 7.7% (4/52) vs. 6.0% (3/50) vs. 16% (9/55) at 3 months

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Datta, 2011	3 months	A vs. B vs. C vs. D: 22% (11/50) vs. 23% (12/52) vs. 16% (8/50) vs. 24% (13/55) lost to followup or had laminectomy and excluded at 3 months	Appears complete	A vs. B vs. C vs. D: Local pain >24 h: 21% (8/39) vs. 17% (7/42) vs. 10% (4/40) vs. 7.1% (3/42) Headache: 38% (15/39) vs. 38% (16/42) vs. 22% (9/40) vs. 31% (31/42) Tinnitus: 2.6% (1/39) vs. 9.5% (4/42) vs. 2.5% (1/40) vs. 7.1% (3/42) Nausea: 15% (6/39) vs. 17% (7/42) vs. 20% (8/40) vs. 17% (7/42) Weight gain: 0% (0/39) vs. 2.4% (1/42) vs. 0% (0/40) vs. 0% (0/42)	Not reported	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Dilke, 1973	RCT	UK Single center Rheumatology clinic	Unilateral sciatica with painful limitation of sciatic or femoral nerve stretch; sciatic scoliosis, appropriate neurologic deficit; duration not specified; imaging findings not required	Diagnostic uncertainty; bilateral manifestations; prior lumbar spine surgery; medical conditions affecting rehabilitation; doubt about the technical success of an injection	Approached: Not reported Eligible: Not reported Randomized: 100 Analyzed: 82 at 3 months	A: Interlaminar epidural injection with 80 mg methylprednisolone in saline (10 ml) B: Interspinous ligament injection with saline (1 ml)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Dilke, 1973	A vs. B: Age (mean): 39 vs. 42 years Male: 53% vs. 58% Duration of symptoms >4 weeks: 90% vs. 90% Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Mefenamic acid; diazepam; bed rest; graded rehabilitation with hydrotherapy; postural exercise; and spinal mobilizing exercise Other patient characteristics: Not reported	Number and frequency of injections: Mean not reported, second injection permitted after 1 week if no improvement Number of levels: Single level Provider experience: Not reported	None reported	Soft tissue injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Dilke, 1973	A vs. B: <u>Pain</u> Pain clearly relieved during admission (clearly relieved, clearly not relieved, or intermediate): 31% (16/51) vs. 8% (4/43), RR 3.37 (95% CI 1.21 to 9.33) Pain assessment "none" (none, not severe, severe): 36% (16/44) vs. 21% (8/38) at 3 months, RR 1.72 (95% CI 0.83 to 3.58) Pain assessment "none" or "not severe": 91% (40/44) vs. 74% (28/38) at 3 months, RR 1.23 (95 % CI 0.10 to 1.52) <u>Other outcomes</u> Full bed rest (days): 8.25 vs. 8.61 (p>0.05) Time to institution of spinal mobility exercises (days): 18.4 vs. 20.4 (NS) Time in hospital (days): 25.2 vs. 28.0 (p>0.05) Not resumed work at 3 months: 8.3% (3/36) vs. 40% (14/35), RR 0.21 (95 % CI 0.07 to 0.66) Analgesic consumption "none" (none, less than daily, daily) at 3 months: 50% (19/38) vs. 38% (11/29), RR 1.32 ((95 % CI 0.75 to 2.32) Underwent surgery at 3 months: 14% (7/51) vs. 21% (10/48), RR 0.66 (95% CI 0.27 to 1.59) Underwent second injection at 3 months: 31% (16/51) vs. 48% (23/48), RR 0.65 (95% CI 0.40 to 1.08) Underwent other conservative treatment at 3 months: 18% (9/51) vs. 29% (14/48), RR 0.61 (95% CI 0.29 to 1.27)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Dilke, 1973	3 months	A vs. B: 18% (18/100) at 3 months	Appears complete	"There were no complications attributable to the injections"	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Gerstzen, 2010	RCT	USA Multicenter Clinical setting not described	18 to 75 years of age; BMI <40; radicular pain score >50 on 0 to 100 VA; epidural corticosteroid injection within 3 weeks to 6 months; normal neurological function; imaging evidence of focal lumbar disc protrusion correlating with clinical symptoms; disc height >50% of normal adjacent discs	Extruded or sequestered disc herniation; sciatica from more than one disc level; axial pain more severe than radicular pain; cauda equina syndrome; progressive neurological deficit; radiological evidence of spondylolisthesis or moderate or severe stenosis at level to be treated; history of previous spinal surgery at or adjacent to level to be treated; spinal fracture; tumor; infection; suspected or planned pregnancy; cardiac pacemaker or defibrillator; spinal cord stimulator; allergy to contrast media or study drugs; severe medical comorbidities; Workman's Compensation or ongoing litigation	Approached: Not reported Eligible: Not reported Randomized: 90 (44 vs. 46) Analyzed: 85 (40 vs. 45) at 2 years, including 12 with missing data	A: Transforaminal epidural injection with corticosteroid, medication type (methylprednisolone acetate, betamethasone, methylprednisolone, triamcinolone acetonide) and dose left to discretion of clinician, with fluoroscopic guidance (n=44) B: Plasma disc decompression procedure with Coblation DLR or DLG Spine Wand surgical device, with fluoroscopic guidance (n=46)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Gerstzen, 2010	A vs. B: Age (mean): 42 vs. 46 years Male: 52% vs. 47% Duration of symptoms (months): median 24 vs. 12 Baseline leg pain (0-100 VAS): 75 vs. 72 Baseline back pain (0-100 VAS): 53 vs. 44 Baseline ODI (0-100): 43 vs. 42	A vs. B: Treatments prior to intervention: Opioid 55% vs. 47% Treatments following intervention: Not specified Other patient characteristics: Full or part-time employment: 65% vs. 62%	Number and frequency of injections: Up to 2 injections 3 weeks apart;75% (30/40) underwent 2 epidural injections Number of levels: Single Provider experience: Not reported	Fluoroscopic guidance	Plasma disc decompression

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Gerstzen, 2010	A vs. B: <u>Pain</u> Leg pain (mean change, 0-100 VAS): at 6 weeks -21 vs. -42 (p=0.002), at 3 months -23 vs. -46 (p=0.0001), at 6 months -21 vs. -47 (p=0.0008) Leg pain improved >=25 points: at 6 months 21% (8/39) vs. 49% (21/43), RR 0.42 (95% CI 0.21 to 0.83); at 1 year 18% (7/39) vs. 44% (19/43), RR 0.42 (95% CI 0.21 to 0.84); at 2 years 21% (8/39) vs. 42% (18/43), RR 0.49 (95% CI 0.24 to 1.0) Back pain (mean change, 0-100 VAS): at 6 weeks 1 vs. -18 (p=0.0005), at 3 months 7 vs. -17 (p=0.0001); at 6 months -0.4 vs. -21 at 6 months (p=0.002) Back pain improved >=12 points: at 6 months 22% (8/36) vs. 49% (19/39), RR 0.46 (95% CI 0.23 to 0.91); at 1 year 11% (4/36) vs. 39% (15/39), RR 0.26 (95 % CI 0.11 to 0.79); at 2 years 17% (6/36) vs. 39% (15/39), RR 0.43 (95% CI 0.19 to 1.0) <u>Function</u> ODI (mean change, 0-100): at 6 weeks -5 vs. -13 at 6 weeks (p=0.002); at 3 months -2 vs. -11 (p=0.002); at 6 months -4 vs. -14 (p=0.002) ODI improved >=13 points: at 6 months15% (6/40) vs. 32% (14/44), RR 0.47 (95% CI 0.20 to 1.10); at 1 year 10% (4/40) vs. 25% (11/44), RR 0.40 (95 % CI 0.14 to 1.16); at 2 years 10% (4/40) vs. 30% (13/44), RR 0.34 (95 % CI 0.12 to 0.95) SF-36 improved >=5 points: at 6 months 21% (8/39) vs. 37% (16/43), RR 0.55 (95% CI 0.27 to 1.14); at 1 year 13% (5/39) vs. 33% (14/43), RR 0.39 (95% CI 0.16 to 0.99); at 2 years 13% (5/39) vs. 33% (14/43), RR 0.39 (95% CI 0.16 to 0.99) <u>Other outcomes</u> Patient satisfaction "extremely satisfied": 15% vs. 38% Did not undergo secondary procedure: 17% vs. 52%, adjusted HR 2.0 (p=0.025) Surgery (not including plasma disc decompression): through 2 years: 5% (2/40) vs.11% (5/45), RR 0.45 (95% CI 0.09 to 2.19)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Gerstzen, 2010	2 years	A vs. B: 15% (6/40) vs. 13% (6/45) at 2 years; 5 post-randomization exclusions	13 patients in group B received epidural injection, 20 patients in group A received plasma disc decompression	A vs. B: Procedure related adverse events: 18% (7/40) vs. 11% (5/45), RR 1.58 (95% CI 0.54 to 4.57) Injection site pain: 5.0% (2/40) vs. 4.4% (2/45), RR 1.12 (95% CI 0.17 to 7.62) Increased radicular pain: 2.5% (1/40) vs. 11% (5/45), RR 0.22 (95% CI 0.03 to 1.85) Increased weakness: 2.5% (1/40) vs. 0% (0/45), RR 3.37 (95% CI 0.14 to 80) Increased back pain: 2.5% (1/40) vs. 8.9% (4/45), RR 0.28 (95% CI 0.03 to 2.36) Lightheadedness: 0% (0/40) vs. 2.2% (1/45), RR 0.37 (95% CI 0.02 to 8.93) Muscle tightness of spasms: 5.0% (2/40) vs. 2.2% (1/45), RR 2.25 (95% CI 0.21 to 24)	ArthoCare Corp	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Ghahreman, 2010 See also Ghahreman, 2011	RCT	Australia Two centers Neurosurgery clinic	Pain radiating into lower limb with lancinating, burning, stabbing, or electric quality; limitation of straight-leg-raise <30° or < 45° with history of lancinating pain & disc herniation; duration not specified; required imaging correlation	Foraminal stenosis; severe motor deficit; history of substance abuse; previous surgery at affected level; conditions that contraindicated spinal injection (e.g., pregnancy, recent infection, or spinal deformity)	Approached: Not reported Eligible: Not reported Randomized: 150 (28 vs. 37 vs. 27 vs. 28 vs. 30) Analyzed: 150 at 12 months, including 22 with missing data (1 vs. 7 vs. 8 vs. 2 vs. 4)	A: Transforaminal injection with 40 mg/ml triamcinolone (1.75 ml) plus 0.5% bupivacaine (0.75 ml), with fluoroscopic guidance (n=28) B: Transforaminal injection of 0.5% bupivacaine (2 ml), with fluoroscopic guidance (n=27) C: Transforaminal injection of normal saline (2 ml), with fluoroscopic guidance (n=37) D: Intramuscular injection of 40 mg/ml triamcinolone (1.75 ml), with fluoroscopic guidance (n=28) E. Intramuscular injection of normal saline (2 ml), with fluoroscopic guidance (n=30)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Ghahreman, 2010 See also Ghahreman, 2011	A vs. B vs. C vs. D vs. E: Age (median): 49 vs. 44 vs. 43 vs. 49 vs. 46 years Male: 61% vs. 51% vs. 63% vs. 54% vs. 70% Duration of symptoms: Mean not reported, range 2 to 560 weeks Baseline leg pain (median, 0-10): 7 vs. 7 vs. 7 vs. 7 vs. 8 Baseline Roland Morris score (median, 0-24): 17 vs. 17 vs. 19 vs. 17 vs. 15	A vs. B vs. C vs. D vs. E: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not specified	Number and frequency of injections: Single injection Number of levels: Appears single Provider experience: Not reported	Fluoroscopic guidance with contrast verification of nerve root for transforaminal injections	Transforaminal injection of normal saline Transforaminal injection of local anesthetic Intramuscular injection of corticosteroid Intramuscular injection of normal saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Ghahreman, 2010 See also Ghahreman, 2011	A vs. B vs. C vs. D vs. E: <u>Pain</u> Pain (mean, 0-10): at baseline 7.0 vs. 7.4 vs. 6.6 vs. 7.6 vs. 7.0; at 1 month 4.1 vs. 6.7 vs. 5.5 vs. 5.9 vs. 6.0, difference -2.9 vs. -0.7 vs. -1.1 vs. -1.7 vs. -1.0, A vs. C (p=0.07); A vs. B, D, or E (p<0.05); for other comparisons: (p>0.05) Achieved >=50% pain relief: at 1 month 54% (15/28) vs. 7.4% (2/27) vs.19% (7/37) vs. 21% (6/28) vs. 13% (4/30): A vs. B: RR, 7.23 (95% CI 1.82 to 28.67; A vs. C: RR, 2.83 (95% CI 1.33 to 6.00; A vs. D: RR, 2.50 (95% CI 1.14 to 5.50; A vs. E, RR 4.02 (95% CI 1.52 to 10.66): (p>0.05); B vs. C, RR 0.39 95% CI 0.89 to 1.73; B vs. D, RR 0.35 (95% CI 0.08 to 1.57); B vs. E, RR 0.56 (95% CI 0.11 to 2.80): C vs. D, RR 0.88 (95% CI 0.33 to 2.34); C vs. E, RR 1.42 (95% CI 0.46 to 4.39); D vs. E, RR 1.61 (95% CI 0.51 to 5.10); no interaction between duration of symptoms, presence of sensory changes or neurologic signs, location [central or paracentral versus foraminal] or level affected, type of herniation (broad-based bulge, focal protrusion, extrusion, sequestration), dimensions of herniation (thickness, cross-section area of herniation or vertebral canal, ratio area of herniation and spinal canal), or presence of degenerative changes; low grade nerve root compression 75% (30/40) and high grade 26% (8/31), p for difference in estimates <0.0005 <u>Function</u> Patient-specified Functional Outcome Scale (median, 0-12): at 1 month 8 vs. 6 vs. 6 vs. 10 vs. 10 (p>0.05) <u>Other outcomes</u> Underwent surgery at 12 months: 36% (10/28) vs. 26% (7/27) vs. 26% (7/27) vs. 21% (6/28) vs. 30% (9/30): A vs. B, RR 1.38 (95% CI 0.61 to 3.09); A vs. C, RR 1.38 (95% CI 0.61 to 3.09); A vs. D, RR 1.67 95% CI 0.70 to 3.10; A vs. E, RR 1.19 (95% CI 0.57 to 2.49); B vs. C, RR 1.00 (95% CI 0.39 to 2.54); B vs. D, RR 0.96 (95% CI 0.36 to 2.53); B vs. E, RR 0.69 (95% CI 0.29 to 1.62); C vs. D, RR 0.96 (95% CI 0.36 to 2.53); C vs. E, RR 0.69 (95% CI 0.29 to 1.62); D vs. E, RR 0.71 (95% CI 0.29 to 1.75) Underwent rescue transforaminal injection with steroid at 12 months: 14% (4/28) vs.67% (18/27) vs. 61% (23/38) vs. 64% (18/28) vs.73% (22/30): A vs. B, RR 0.21 (95% CI 0.83 to 0.55); A vs. C, RR 0.24 (95% CI 0.09 to 3.09); A vs. D, RR 0.22 95% CI 0.09 to 0.57; A vs. E, RR 0.19 (95% CI 0.07 to 0.50); B vs. C, RR 1.10 (95% CI 0.76 to 1.60); B vs. D, RR 1.04 (95% CI 0.71 to 1.52); B vs. E, RR 0.91 (95% CI 0.65 to 1.28); C vs. D, RR 0.94 (95% CI 0.65 to1.37); C vs. E, RR 0.83 (95% CI 0.59 to 1.62); D vs. E, RR 0.83 (95% CI 0.59 to 1.12) No differences in health care utilization No effect of chronicity on response to treatment

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Ghahreman, 2010 See also Ghahreman, 2011	12 months	A vs. B vs. C vs. D vs. E: 3.6% (1/28) vs. 26% (7/27) vs. 22% (8/37) vs. 7.1% (2/28) vs. 13% (14/30) at 12 months	Appears complete	"No complications occurred that could be attributed to the treatment" 1 case of bladder incontinence after transforaminal injection of local anesthetic	Not reported	Good

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Ghai, 2014	RCT	India Single center Pain clinic	18 to 65 years, with chronic (>3 months) low back pain and unilateral lumbosacral radicular pain, not responding to medications and physical therapies, pain score >=50 on a 0 to 100 VAS at baseline were eligible; MRI was performed for correlation with symptoms	Clinically significant or unstable medical or psychiatric illness, previous surgery on the lumbar spine, facet joint arthropathy, spinal canal stenosis, unstable neurological deficits, or cauda equine syndrome. prior lumbar epidural steroid injection, corticosteroids or anesthetics allergy, taking anticoagulants or bleeding diathesis, taking systemic corticosteroids, pregnant or lactating women	Approached: 124 Eligible: Not reported Randomized: 62 (32 vs. 30) Analyzed: 62 (32 vs. 30)	A. Parasagittal epidural injection with 80 mg methylprednisolone (2 ml) plus normal saline) 2 ml B. Transforaminal epidural injection with 80 methylprednisolone (2 ml) plus normal saline (2 ml), with fluoroscopic guidance
Ghai, 2013	RCT	India Single center Pain clinic	Low back pain with unilateral lumbosacral radicular pain for at least 3 months (MRI performed in all patients)	Somatic referred pain	Approached: 40 Eligible: Not reported Randomized: 37 (19 vs. 18) Analyzed: 37 at 6 months	A: Parasagittal interlaminar injection with 80 mg methylprednisolone (2 ml) plus normal saline (2 ml), with fluoroscopic guidance B: Midline interlaminar injection with 80 mg methylprednisolone (2 ml) plus normal saline (2 ml), with fluoroscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Ghai, 2014	A vs. B: Age (mean): 43 vs. 46 years Male: 53% vs. 63% Duration of symptoms (months); 25 vs. 30 Baseline pain (0-100 VAS): 73 vs. 74 Modified ODI (0 to 100): 31 vs. 29	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 58 vs. 60 injections (p = 0.72), mean 1.84 vs. 1.92 procedures per year Number of levels: Appears to be single Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space	Head-to-head comparison of alternative epidural steroid injection methods
Ghai, 2013	A vs. B: Age (mean): 41 vs. 42 years Male: 68% vs. 50% Duration of symptoms (months); 13 vs. 14 Baseline pain (0-100 VAS): 69 vs. 71 Modified ODI (0 to 100): 42 vs. 49	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Mean 1.53 vs. 2.28 over 6 months (up to 3 injections at least 15 days apart if pain relief <50%) Number of levels: Not reported, levels could differ on subsequent injections Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space	Head-to-head comparison of alternative epidural steroid injection methods

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Ghai, 2014	A vs. B: <u>Pain</u> Pain score (mean, VAS 0-100, estimated from graph): at baseline, 73 vs. 73 (p=0.56); at 15 days, 38 vs. 45 (p=0.63); at 1 month, 36 vs. 39 (p=0.61); at 2 months, 36 vs. 36 (p=0.59); at 3 months, 35 vs. 35 (p=0.64); at 6 months, 34 vs. 34 (p=0.56); at 9 months, 33 vs. 33 (p=0.23); at 12 months, 33 vs. 31 (p=0.79) <u>≥</u>50% pain relief from baseline using VAS: at 15 days, 65.6% vs. 50% (p=0.3); at 1 month, 72% vs. 63% (p=0.59); at 2 months, 69% vs. 73% (p=0.78); at 3 months, 78% vs. 77% (p=1.0); at 6 months, 75% vs. 77% (p=1.0); at 9 months, 78% vs. 73% (p=0.77); at 12 months, 69% vs. 77% (p=0.57) <u>Function</u> Modified ODI (estimated from graph): at baseline, 32 vs. 29 (p=0.18); at 15 days, 21 vs. 20 (p=0.29); at 1 month, 19 vs. 18 (p=0.38); at 2 months, 19 vs. 17 (0.38); at 3 months, 20 vs. 18 (p=0.60); at 6 months, 19 vs. 17 (p=0.36); at 9 months, 18 vs. 17 (p=0.52); at 12 months, 18 vs. 17 (p=0.45) <u>Other outcomes</u>: Patient satisfaction: Patient Global Impression of Change Scale (7-point scale where 1-3 = improved, 4 = no change, 5-7 = worse since study start): % improved at 3 months, 78% (25/32) vs/ 77% (23/30); at 6 months, 75% (24/32) vs. 80% (24/30); at 9 months, 78% (25/32) vs. 77% (23/30); at 12 months, 78% (25/32) vs. 80% (24/30) (p>0.05 for all)
Ghai, 2013	A vs. B: <u>Pain</u> Pain score (mean, VAS 0-100, estimated from graph): at baseline, 69 vs. 71; at 15 days, 29 vs. 49; at 1 month, 28 vs. 50; at 3 months, 30 vs. 48; at 6 months, 31 vs. 51, (p<0.05 at all time points) 50% pain relief: at 15 days 79%(15/19) vs. 39% (7/18) RR, 2.03 (95 % CI 1.09 to 3.78); at 1 month 79% (15/19) vs. 39% (7/18) RR 2.03 (95 % CI 1.09 to 3.78); at 3 months 79% (15/19) vs. 39% (7/18) RR, 2.03 (95 % CI 1.09 to 3.78); at 6 months 68% (13/19) vs.17% (3/18), RR 4.1 (95% CI 1.4 to 12) <u>Function</u> ODI (mean, 0-100, estimated from graph): at baseline, 42 vs. 49; at 15 days, 27 vs. 40; at 1 month, 27 vs. 41; at 3 months, 30 vs. 42; at 6 months, 30 vs. 43, (p<0.05 at all time points)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Ghai, 2014	12 months, but 3 month followup is primary outcome	None reported	Appears complete	No patient reported any swelling, redness, or persisting pain at the injection site.	None	Good
Ghai, 2013	6 months	None reported	Appears complete	None reported	None	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Gharibo, 2011	RCT	US Single center Pain clinic	Low back pain radiating to one lower extremity for >1 month and <1 year, due to disc disease; failed analgesic and nonpharmacologic therapy; imaging correlation on CT or MRI; unable to tolerate physical therapy; no benefit from physical therapy	Lumbar spine surgery or epidural steroid injections within 6 months; multilevel degenerative spine disease; unstable spine; spondylolisthesis > grade 1; spondylolysis, cauda equina syndrome; arachnoiditis, progressive neurologic deficit; central spinal canal stenosis; active cancer diagnosis; history of substance abuse; current psychiatric co-morbidity; pregnant; contrast, steroid, or local anesthetic allergy; ongoing medical legal or workman's compensation	Approached: 80 Eligible: 46 Randomized: 42 (21 vs. 21) Analyzed: 38 (20 vs. 18) at 10-16 days (including 3 missing data)	A: Transforaminal epidural injection with 40 mg triamcinolone diacetate (1 ml) plus 0.25% bupivacaine (1 ml) at two levels, with fluoroscopic guidance B: Interlaminar epidural injection with 80 mg triamcinolone diacetate (2 ml) plus 0.25% bupivacaine (2 ml), with fluoroscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Gharibo, 2011	A vs. B: Age (mean): 48 vs. 51 years Male: 55% vs. 72% Duration of symptoms: Not reported Baseline pain (0-10): 6.4 vs. 7.0 Baseline ODI (0-50): 38 vs. 38	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 1/20 vs. 3/18 underwent two procedures Number of levels: Two levels (transforaminal) vs. single level (interlaminar) Provider experience: Single provider with over 10 years experience	Fluoroscopy with contrast verification in epidural space	Head-to-head comparison of alternative epidural steroid injection methods

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Gharibo, 2011	A vs. B: <u>Pain</u> Pain (mean, 0-10 NRS): 6.4 vs. 7.0 at baseline, 1.7 vs. 3.9 at 10-16 days (p<0.05) <u>Function</u> ODI (mean, 0-50): 38 vs. 38 at baseline, 22 vs. 13 at 10-16 days (p<0.05) <u>Other outcomes</u> Depression (scale not reported): 4.1 vs. 4.4 at baseline, 1.7 vs. 2.2 at 10-16 days (p<0.05) Walking distance (blocks): 8.9 vs. 8.1 at baseline, 11.8 vs. 10.6 at 10-16 days (p<0.05 base on 1-sided test)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Gharibo, 2011	10-16 days	A vs. B: 4.8% (1/21) vs. 10% (2/21) at 10-16 days	2 crossovers in interlaminar injection group after 2 failed injections; one patient excluded for receiving epidural steroid injection outside of protocol	Not reported	None	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Habib, 2013	RCT	Israel Single center Hospital	Patients >18 years, low back pain due to radiculopathy of at least one month's duration that did not respond to physical therapy or nonsteroidal anti-inflammatory drugs (if not contraindicated); imaging findings not required	Having had an epidural corticosteroid, systemic, intra-articular, and/or intramuscular injection; nasal spray, eye drops, or inhalation of steroid compounds during the previous three months; evidence of acute illness (inflammatory or noninflammatory); inflammatory back pain; uncontrolled hypertension; uncontrolled diabetes; anticoagulant treatment; bleeding tendency; allergy to corticosteroids; and/or pregnancy	Approached: Not reported Eligible: 50 Randomized: 42 (21 vs. 21) Analyzed: 35 at 4 w	A: Epidural injection with 80 mg methylprednisolone acetate, approach and other details not provided (n=21) B: Epidural injection with 40 mg methylprednisolone acetate, approach and other details not provided (n=21)
Helliwell, 1985	RCT	UK Single center Rheumatology clinic	Low back pain for >2 months with pain in the sciatic or femoral nerve distribution accompanied by dural tension signs or a neurological deficit consistent with lumbar root compression; radiograph of lumbar spine before randomization	Diagnostic uncertainty; pregnant; prior lumbar spine surgery or the development of progressive neurologic impairment	Approached: Not reported Eligible: Not reported Randomized: 39 (20 vs. 19) Analyzed: 39 at 3 months	A: Interlaminar epidural injection with 80 mg methylprednisolone in saline (10 ml) (n=20) B: Interspinous ligament injection with saline (5 ml) (n=19)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Habib, 2013	A vs. B: Age (mean): 53 vs. 51 Male: 62% vs. 76% Duration of back pain: 2.9 vs. 3.4 years Baseline VAS (0-100): 80 vs. 78	A vs. B: Treatments prior to intervention: Previous back surgery 1 vs 0; Previous epidural injection 4 vs. 2 Treatments following intervention: Not specified Other patient characteristics: Serum cortisol level at baseline 11.1 vs. 13.6 ng/mL	Number and frequency of injections: 1 Number of levels: 1-2 Provider experience: Experienced anesthesiologist	Not reported	Epidural injection with different doses of corticosteroid
Helliwell, 1985	A vs. B: Age (mean): 45 vs. 47 years Male: 25% vs. 20% Duration of symptoms (months): 8.5 vs. 13 Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single Number of levels: Single Provider experience: Not reported	Not reported	Soft tissue injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Habib, 2013	A vs. B Pain ≥30% improvement in 0-100 VAS: 62% (13/21) vs. 47% (9/19) at w 1 (p=0.362); 56% (10/18) vs. 35% (7/20) (p=0.210) at w 3, 39% (7/18) vs. 6% (1/17) at w 4 (p=0.049) Other outcomes Serum cortisol levels and number of patients with secondary adrenal insufficiency (serum corticol <18 ng/ml 30 minutes after ACTH stimulation test): 86% (18/21) vs. 53% (10/19) at w 1 (p=0.024), 22% (4/18) vs. 15% (3/20) at w 3 (p=0.87), 17% (3/18) vs. 12% (2/17) at w 4 (p=0.72)
Helliwell, 1985	A vs. B: Pain Pain, mean change from baseline (0-10 VAS, estimated from figure): at 1 month -2.6 vs. -0.7; at 3 months -2.7 vs. -0.3 (p<0.01 at both time points) Other outcomes Analgesic consumption decreased by >=50%: at 3 months 64% (7/11) vs. 40% (4/10), RR 1.6 (95% CI 0.69 to 4.1) Overall outcome "definite improvement" (vs. no improvement): at 3 months 70% 14/20 vs. 26% (5/19) RR, 2.7 (95% CI 1.3 to 6.2)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Habib, 2013	4 weeks	A vs. B: 14% (3/21) vs. 19% (4/21)	Appears complete	Not reported	Departmental funding	Poor
Helliwell, 1985	3 months	Not reported	Appears complete	None reported	Not reported	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Iversen, 2011	RCT	Norway Multi-center Clinical setting unclear	Unilateral lumbar radiculopathy >12 weeks with leg pain below the knee; leg pain worse than back pain; age 20 to 60 years; MRI or CT performed in all patients	Cauda equina syndrome; severe paresis; severe pain; prior spinal injection or surgery; deformity; pregnancy; breast feeding; warfarin therapy; treatment with non-steroidal anti-inflammatory drugs; body mass index >30; poorly controlled psychiatric conditions with possible secondary gain, or severe comorbidity; severe intraspinal pathology	Approached: 461 Eligible: 133 Enrolled: 116 (37 vs. 39 vs. 40) Analyzed: 116 (37 vs. 39 vs. 40) at 52 weeks (including 4 missing data)	A: Caudal epidural injection with 40 mg triamcinolone in 0.9% saline (29 ml), with ultrasound guidance (n=37) B: Caudal epidural injection with 0.9% saline (30 ml), with ultrasound guidance (n=39) C: Subcutaneous injection superficial to the sacral hiatus and outside spinal canal with 0.9% saline (2 ml), with ultrasound guidance (n=40)
Jeong, 2007	RCT	Korea Single center Radiology clinic	Lumbosacral radiculopathy; imaging (CT or MRI) documentation of nerve root compression with subarticular or paracentral disk herniation or central canal and/or lateral recess stenosis, based on consensus of 3 radiologists; duration of symptoms not specified	Not reported	Approached: Not reported Eligible: Not reported Randomized: 239 (127 vs. 112) Analyzed: 222 (116 vs. 106) at mid-term (>6 m) followup	A: Ganglionic transforaminal epidural injection with 40 mg triamcinolone acetonide (1 ml) plus 0.5% bupivacaine (0.5 cc), with fluoroscopic guidance (n=127) B: Preganglionic transforaminal epidural injection with 40 mg triamcinolone acetonide (1 ml) and 0.5% bupivacaine (0.5 cc), with fluoroscopic guidance (n=112)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Iversen, 2011	A vs. B vs. C: Age (mean): 40 vs. 43 vs. 43 years Male: 54% vs. 62% vs. 60% Duration of leg pain (weeks): 42 vs. 57 vs. 27 Baseline back pain (0-100 VAS): 47 vs. 50 vs. 46 Baseline leg pain (0-100 VAS): 50 vs. 54 vs. 48 Baseline ODI (0-50): 32 vs. 31 vs. 26	A vs. B vs. C: Treatments prior to intervention: Use of morphine: 24% vs. 18% vs. 15% Treatments following intervention: Not reported Other patient characteristics: Physically demanding work: 57% vs. 46% vs. 47% Received sickness benefit: 68% vs. 67% vs. 55% Fear Avoidance Beliefs Questionnaire (FABQ) work: 24 vs. 25 vs. 22 FABQ physical activity: 12 vs. 14 vs. 13	Number and frequency of injections: 2 injections within 2 weeks on all patients unless pain recovered prior to 2nd injection Number of levels: Not reported Provider experience: "Experienced" anesthesiologist	Ultrasound used to identify sacral hiatus	Caudal epidural injection with saline Soft tissue injection with saline
Jeong, 2007	A vs. B: Age (mean): 50 vs. 49 years Male: 40% vs. 48% Spinal stenosis: 18% vs. 20% Herniated disc: 82% vs. 80% Duration of symptoms <6 months: 64% vs. 56% Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: 2-5 years	Fluoroscopic guidance with contrast verification	Head-to-head comparison of alternative transforaminal epidural steroid injection techniques

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Iversen, 2011	A vs. B vs. C: <u>Pain</u> Leg pain: at 6 weeks 3.2 (-9.1 to 16) ; at 12 weeks 2.5 (-9.6 to 15); at 52 weeks 3.1 (-9.6 to 16) Low back pain: at 6 weeks -5.0 (-17 to 6.7); at 12 weeks -7.8 (-19 to 3.8); at 52 weeks -2.0 (-14 to 10) EuroQol: at 6 weeks -0.02 (-0.13 to 0.09); at 12 weeks -0.05 (-0.17 to 0.06); at 52 weeks -0.01 (-0.12 to 0.11) A vs. C: <u>Function</u> ODI: (mean difference, 0-50) A vs B: at 6 weeks; -0.5 (-6.3 to 5.4); at 12 weeks; 1.4 (-4.5 to 7.2); at 52 weeks; -1.9 (-8.0 to 4.3); A vs. C: at 6 weeks; -2.9 (-9.7 to 3.0); at 12 weeks; 4.0 (-1.9 to 9.9); at 52 weeks; 1.9 (-4.2 to 8.0) EuroQol: (mean difference, -0.594 to 1) A vs. B: at 6 weeks; -0.02 (-0.13 to 0.09); at 12 weeks; -0.05 (-0.17 to 0.06); at 52 weeks; -0.01 (-0.12 to 0.11). A vs. C: at 6 weeks; -0.05 (-0.16 to 0.06); at 12 weeks; -0.12 (-0.23 to -0.00); at 52 weeks; -0.05 (-0.17 to 0.06) <u>Other outcomes</u> Morphine use at 6 weeks: 8.1% (3/37) vs. 17% (6/35) vs. 11% (4/37): A vs. B RR 0.47 (95% CI 0.13 to 1.74); A vs. C RR 0.75 (95% CI 0.18 to 3.12); B vs. C RR 1.59 (95 % CI 0.49 to 5.15) Receiving sickness benefit at 52 weeks: 32% (11) vs. 30% (10) vs. 22% (7) (p=0.69) Underwent back surgery: 2.7% (1/37) vs. 15% (6/39) vs. 20% (8/40) (p=0.07): A vs. B, RR 1.72 (95% CI 0.72 to 4.12); A vs. C, RR 1.33 (95% CI 0.61 to 2.88); B vs. C, RR 0.77 (95% CI 0.29 vs. 2.01)
Jeong, 2007	A vs. B: <u>Pain</u> Overall results excellent (4 category scale poor, fair, good, excellent): 47% (56/127) vs. 73% (82/112) at 1 month, RR 0.60 (95% CI 0.48 to 0.75); 34% (39/116) vs. 37% (39/106) at mid-term (> 6 month) follow-up, RR 0.91 (95% CI 0.64 to 1.31) Overall results good or excellent: at 1 month 71% (90/127) vs. 88% (99/112), RR 0.80 (95% CI 0.70 to 0.91); at mid-term follow-up 67% (78/116) vs. 60% (64/106), RR 1.11 (95% CI 0.91 to 1.36) Age, sex, duration of symptoms, cause of radiculopathy were not statistically significant predictors for effectiveness of injection at 1 month or mid-term follow-up

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Iversen, 2011	52 weeks	A vs. B: 0% (0/37) vs. 5.1% (2/39) vs. 5.0% (2/40) at 52 weeks	5 patients did not receive allocated intervention (1 vs. 3 vs. 1), 7 discontinued intervention (2 vs. 4 vs. 1); no crossovers	6 had local pain with injection	North Norway Regional Health Authority and Health Region Nord-Trondelag, Norway	Good
Jeong, 2007	Mean 373 days (range 216-547) post-injection	A vs. B: 7% (17/239) at midterm followup	Appears complete	None reported	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Kang, 2011	RCT	South Korea Single center Pain clinic	Signs and symptoms consistent with nerve root entrapment at neural foramen; radicular leg pain; positive straight leg raise; at least single level disc herniation on MRI correlating with symptoms; age 18 to 60 years; duration not specified	Spinal stenosis; allergic reaction to local anesthetics or corticosteroids; contraindications to epidural steroid injections; epidural steroid injection within 6 months; previous lumbar spine surgery; unstable neurological deficits; cauda equina syndrome	Approached: Not reported Eligible: Not reported Randomized: 160 (40 vs. 40 vs. 40 vs. 40) Analyzed: 160 at 2 weeks	A: Transforaminal epidural injection with 40 mg triamcinolone plus 1% lidocaine (total 3 ml), with fluoroscopic guidance (n=40) B: Transforaminal epidural injection with 20 mg triamcinolone plus 1% lidocaine (total 3 ml), with fluoroscopic guidance (n=40) C: Transforaminal epidural injection with 10 mg triamcinolone plus 1% lidocaine (total 3 ml), with fluoroscopic guidance (n=40) D: Transforaminal epidural injection with 5 mg triamcinolone plus 1% lidocaine (total 3 ml), with fluoroscopic guidance (n=40)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Kang, 2011	A vs. B vs. C vs D: Age (mean): 47 vs. 53 vs. 52 vs. 53 years Male: 40% vs. 42% vs. 38% vs. 35% Duration of symptoms (days): 37 vs. 33 vs. 42 vs. 33 Baseline pain: 7.3 vs. 7.2 vs. 7.0 vs. 7.0 Baseline function: Not reported	A vs. B vs. C vs. D: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 2 injections 1 weeks apart Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification	Head-to-head comparison of alternative corticosteroid doses

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Kang, 2011	A vs. B vs. C vs. D: <u>Pain</u> Pain (0-10 VAS): at baseline 7.3 vs. 7.2 vs. 7.0 vs. 7.0; at 1 week 3.8 vs. 3.9 vs. 4.3 vs. 5.4; at 2 weeks 3.2 vs. 3.3 vs. 3.4 vs. 3.9, (p>0.05) Pain relief (>=67% improvement in VAS pain): at 1 week 75% (30/40) vs.70% (28/40) vs. 65% (26/40) vs. 45% (18/40): A vs. B, RR 1.07 (95% CI 0.88 to 1.40); A vs. C, RR 1.15 (95% CI 0.86 to 1.54); A vs. D, RR 1.67 (95% CI 1.13 to 2.46); B vs. C RR, 1.08 (95% CI 0.79 to 1.47); B vs. D, RR 1.56 (95% CI 1.04 to 2.32); C vs. D, RR 1.44 (95% CI 0.96 to 2.18) (p<0.05 for A, B, or C vs. D); at 2 weeks 85% (34/40) vs. 80% (32/40) vs. 75% (30/40) vs. 68% (27/40): A vs. B, RR 1.06 (95% CI 0.87 to 1.30); A vs. C, RR 1.13 (95% CI 0.91 to 1.41); A vs. D, RR 1.26 (95% CI 0.98 to 1.62); B vs. C, RR 1.07 (95% CI 0.84 to 1.35); B vs. D, RR 1.19 (95% CI 0.91 to 1.54); C vs. D, RR 1.11 (95% CI 0.84 to 1.49)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Kang, 2011	2 weeks	None reported	Appears complete	Facial flushing (n=2) and itching (n=1); groups not reported	No funding received	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Karppinen, 2001 See also Karpinnen, 2001	RCT	Finland Single center Radiology department	Unilateral back pain radiating dermatomally below knee; duration 3 to 28 weeks; leg pain intensity at least equal to back pain intensity; MRI scans at baseline (findings for inclusion not specified)	Prior back surgery; application for early retirement; clinical depression; anticoagulation treatment; unstable diabetes; epidural injection in past 3 months; pregnant; allergy to study drugs; rare causes of sciatica such as synovial cysts; nondegenerative spondylolisthesis	Approached: 277 Eligible: 171 Randomized: 163 Analyzed: 158 (78 vs. 80) at 12 months	A: Transforaminal (periradicular) injection with 2-3 cc of methylprednisolone 40 mg/cc plus bupivacaine 5 mg/cc, with fluoroscopic guidance (n=78) B: Transforaminal (periradicular) injection with isotonic (0.9%) saline (2-3 cc), with fluoroscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Karppinen, 2001 See also Karpinnen, 2001	A vs. B: Age (mean): 44 vs. 44 years Male: 64% vs. 58% Duration of symptoms (months): 2.4 vs. 2.6 Baseline leg pain (0 to 100 VAS): 71 vs. 75 Baseline back pain (0 to 100 VAS): 53 vs. 60 Baseline ODI (0-100): 43 vs. 44	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Back school instructions by physiotherapist at 2 weeks; pain medication and physiotherapy for persisting sciatic pain; referral to neurosurgeon for severe sciatic pain and disability Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Experienced radiologist	Fluoroscopic guidance with contrast verification of nerve root site	Transforaminal epidural injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Karppinen, 2001 See also Karpinnen, 2001	A vs. B: *(difference ANCOVA adjusted for level of symptomatic disc and days on sick leave)* <u>Pain</u> Leg pain (0-100 VAS): 71 vs. 75 at baseline; 39 vs. 54 at 2 w, difference -12 (95% CI -23.4 to 1.6); 37 vs. 44 at 4 w, difference -2.3 (95% CI -13.4 to 8.7); 31 vs. 34 at 3 m, difference 0.5 (95% CI -11 to 12); 31 vs. 22 at 6 m, difference 16 (95% CI 5.6 to 27); 24 vs. 24 at 12 m, difference 5.3 (-5.0 to 16); by MRI subgroups: bulges no differences at any time point; contained herniation difference -24 (95% CI -8 to -41) at 2 w; -19 (95% CI -36 to -3) at 4 w; -1.4 (95% CI -23 to 20) at 3 m; 22 (95% CI 5 to 40) at 6 m; 0.3 (95% CI -16 to 16) at 1 y Back pain (0-100 VAS): 53 vs. 60 at baseline; 26 vs. 36 at 2 w, difference -5.8 (95% CI -17 to 5.1); 27 vs. 31 at 4 w, difference 6.1 (95% CI -5.0 to 17); 26 vs. 23 at 3 m, difference 12 (95% CI 1.0 to 24); 23 vs. 20 at 6 m, difference 14 (95% CI 2.4 to 25); 19 vs. 19 at 12 m, difference 8.4 (95% CI -2.1 to 19); extrusions no differences except at 6 m, difference 17 (95% CI 1 to 32); disc level L3-L4/L4-L5 -25 difference -25 (955 CI -40 to -10) at 2w, -20 (95% CI -35 to 5) at 4 w, no differences at other time points >75% improvement in leg pain (only reported for some subgroups): contained herniations: 35% (9/26) vs. 9% (2/23) at 2 w (p=0.04), otherwise no differences; extrusions: No differences at any time point; disc level L3-L4/L4-L5: 68% (21/36) vs. 31% (16/51) at 4 w (p=0.02), otherwise no differences <u>Function</u> ODI (0-100): 43 vs. 44 at baseline; 29 vs. 34 at 2 w, difference -5.1 (95% CI -10 to 0.3); 27 vs. 29 at 4 w, difference -1.5 (95% CI -7.3 to 4.4); 23 vs. 23 at 3 m, difference 1.3 (95% CI -6.1 to 8.6); 19 vs. 16 at 6 m, difference 5.9 (95% CI -0.7 to 12); 16 vs. 16 at 12 m, difference 0.4 (95% CI -6.2 to 7.0); by MRI subgroups: bulges no differences at any time point; contained herniation difference -8.0 (-16 to 0.3) at 2 w, -2.7 (95% CI -10 to 5) at 4 w, 2.3 (95% CI -9 to 13) at 3 m, 14 (95% CI 3 to 24) at 6 m, 1.2 (95% CI -9 to 12) at 1 y; extrusion no differences at any time point; disc level L3-L4 or L4-L5 -9.6 (95% CI -17 to -2) at 2 w, no differences at other time points <u>Other outcomes</u> Sick leave (days/month): 8.9 vs.10 at 4 w, difference -0.5 (95% CI -3.9 to 4.9); 7.3 vs. 7.4 at 3 m, difference -0.2 (95% CI -4.4 to 3.9); 3.6 vs. 4.9 at 6 m, difference 1.7 (95% CI -1.7 to 5.1); 1.9 vs. 1.2 at 12 m, difference -0.6 (95% CI -2.4 to 1.2) Therapy visits: 0.4 vs. 1.9 at 4 w, difference 1.7 (95% CI -0.5 to 3.9); 3.7 vs. 5.9 at 12 m, difference 1.7 (95% CI -2.9 to 6.3) Underwent surgery: 22% (18/80) vs. 19% (15/80) at 12 m, RR 1.2 (95% CI 0.65 to 2.21); contained herniation subgroup 20% vs. 42% (p=0.10), extrusion subgroup 32% vs. 13% (p=0.05)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Karppinen, 2001 See also Karpinnen, 2001	1 year	A vs. B: 2/80 (2.5%) vs. 0/80 (0%); 3 other exclusions because neurogram findings were not typical	Complete	Retroperitoneal hematoma in one patient on anticoagulant therapy in group A	Private foundation and government agencies in Finland; International Spinal Intervention Society	Good

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Kennedy, 2014	RCT	USA Two centers Rehabilitation or spine surgery clinic	Unilateral radicular pain with pain intensity ≥4 on 0-10 scale; <6 months duration; MRI single level below L3 corresponding with symptoms; appropriate for surgery if injection failed	Back pain greater than leg pain; nonradicular pain; unclear diagnosis; more than one potential pain generator on MRI; lumbar stenosis; prior surgery; prior spine injection; conditions increasing injection risk (bleeding tendencies, workers compensation, pregnancy, litigation)	Approached: Not reported Eligible: 81 Randomized: 78 (41 vs. 37) Analyzed: Unclear at 6 months	A: Transforaminal epidural injection with 15 mg dexamethasone (1.5 ml) plus 1% lidocaine (2 ml), with fluoroscopic guidance B: Transforaminal epidural injection with 60 mg triamcinolone (1.5 ml) plus 1% lidocaine (2 ml), with fluoroscopic guidance
Kim, 2011	RCT	USA Single center Pain clinic	Lumbar radicular symptoms below the knee corresponding to MRI findings; ≥18 year of age; pain ≥6 months; failed medication and physical therapy	Litigation; history of psychopathology; Beck Depression Inventory <15; history of substance abuse; contraindications to intra-axial procedures	Approached: Not reported Eligible: Not reported Randomized: 61 (31 vs. 30) Analyzed: 60 (30 vs. 30)	A: Interlaminar epidural injection with 15 mg dexamethasone phosphate, 0.25% bupivacaine (2 ml), and saline (total 10 ml), with fluoroscopic guidance (n=30) B: Interlaminar epidural injection with 80 mg methylprednisolone acetate, 0.25% bupivacaine (2 ml), and saline (total 10 ml), with fluoroscopic guidance (n=30)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Kennedy, 2014	A vs. B: Age (mean): 36 vs. 36 years Male: 66% vs. 65% Duration of symptoms (weeks): 10 vs. 8.6 Baseline pain (0-10): 6.3 vs. 6.5 Baseline ODI (0-100): 46 vs. 42	A vs. B: Treatments prior to intervention: No differences between groups; no formal treatment program prior to intervention Treatments following intervention: Not specified L4/L5: 15% vs. 14% L5/S1: 56% vs. 54% S1/S2: 29% vs. 32% Disc extrusion: 27% vs. 46%	Number and frequency of injections: Up to 3 injections over 6 months; 54% vs. 62% received 1 injection, 29% vs. 32% 2 injections, 17% vs. 2.7% 3 injections Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification	Head-to-head comparison of alternative corticosteroids
Kim, 2011	A vs. B: Age (mean): 66 vs. 64 years Male: 13% vs. 20% Duration of symptoms: Not reported Baseline pain (0-100 VAS): 78 vs. 77 Baseline function: Not reported	A vs. B: Treatment prior to intervention: Not specified Treatments following intervention: not specified Other patient characteristics: Not reported	Number and frequency of injections: Two injections, within 1-2 months Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification in epidural space	Head-to-head comparison of alternative corticosteroids

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Kennedy, 2014	A vs. B: <u>Pain</u> Pain (mean 3 day average NRS, 0-10): 7.0 vs. 6.9 at baseline 4.1 vs. 4.1 at 7-14 days; 1.6 vs. 1.8 at 3 months; 1.4 vs. 1.2 at 6 months Pain improved >50%: 32% (13/41) vs. 43% (16/37) at 7-14 days, RR 0.73 (95% CI 0.41 to 1.31)27; 73% (30/41) vs. 73% (27/37) at 3 months, RR 1.0 (95% CI 0.77 to 1.31); 73% (30/41) vs. 76% (28/37) at 6 months, RR 0.97 (95 % CI 0.75 to 1.25) <u>Function</u> ODI improved >51%: 27% (11/41) vs. 35% (13/37) at 7-14 days, RR 0.60 (95% CI 0.30 to 1.92); 68% (28/41) vs. 68% (30/37) at 3 months, RR 0.84 (95% CI 0.65 to 1.09); 71% (27/41) vs. 65% (24/37) at 6 months, RR 1.07 (95% CI 0.78 to 1.46) <u>Other outcomes</u> Underwent surgery: 15% (6/41) vs. 19% (7/37) at 6 months, RR 0.77 (95% CI 0.29 to 2.09)
Kim, 2011	A vs. B: <u>Pain</u> Pain (0-100 VAS): 78 vs. 77 at baseline, 61 vs. 54 at 1-2 months; percent change from baseline -20% vs. -27% (p=0.37) Decrease in pain: 90% (27/30) vs. 87% (26/30), RR 1.04 (95% CI 0.86 to 1.25) <u>Other outcomes</u> Pain medication use, emergency room visits for pain, new treatment for pain: No differences, data not provided

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Kennedy, 2014	6 months after last injection	Unclear	Appears complete	Not reported	International Spine Intervention Society	Fair
Kim, 2011	1-2 months (mean 41 vs. 51 days)	A vs. B: 3.2% (1/31) excluded from analysis from dexamethasone group	Appears complete	"No complications were reported including new neurological symptoms or new areas of pain." 1 patient excluded for inadvertant dexamethasone injection intrathecally; no complications seen	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Klenerman, 1984	RCT	UK Single center Rheumatology clinic	Unilateral sciatica with or without objective neurological signs; no previous treatment in a hospital for backs; symptoms ≤6 months	Not reported	Approached: Not reported Eligible: Not reported Randomized: 74 Analyzed: 63 (19 vs. 16 vs. 16 vs. 12) at 2 months	A: Epidural injection with 80 mg methylprednisolone plus normal saline (20 ml total) (n=19) B: Epidural injection with 0.25% bupivacaine (20 ml) (n=16) C: Epidural injection with normal saline (20 ml) (n=16) D: Interspinous ligament needling without injection (n=12)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Klenerman, 1984	A vs. B vs. C vs. D: Age: Not reported Male: Not reported Duration of symptoms: Not reported (≤6 months by inclusion criteria) Baseline pain (0-100 VAS): 48 vs. 53 vs. 65 vs. 65 Baseline function: Not reported	A vs. B vs. C vs. D: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single Number of levels: Single level Provider experience: Not reported	Not reported	Epidural injection with local anesthetic of saline, or soft tissue needling without injection

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Klenerman, 1984	A vs. B vs. C vs. D: <u>Pain</u> Pain (0-100 VAS, estimated from graph): at baseline 48 vs. 53 vs. 65 vs. 65; at 2 weeks 30 vs. 39 vs. 39 vs. 53; at 2 months 25 vs. 19 vs. 20 vs. 25 <u>Global assessment</u> "Improved" or "cured" (failed, improved, cured) at 2 months: 79% (15/19) vs. 69% (11/16) vs. 69% (11/16) vs. 83% (10/12): A vs. B: RR 0.19 (95% CI 0.77 to 1.72); A vs. C RR 1.15 (95% CI 0.66 to 1.60); A vs. D RR 0.95 (95% CI 0.67 to 1.34); B vs. C: RR 1.00 (95% CI 0.77 to 1.72); B vs. D: RR 0.83 (95% CI 0.54 to 1.25); C vs. D RR 0.83 (95% CI 0.54 to 1.25) <u>Other outcomes</u> Underwent surgery: 0% (0/19) vs. 12% (2/16) vs. 0% (0/16) vs. 0% (0/12): A vs. B: RR 0.17 (95% CI 0.00 to 3.30); A vs. C RR 0.85 (95% CI 0.02 to 40.60); A vs. D RR 0.65 (95% CI 0.01 to 30.77); B vs. C: RR 5.00 (95% CI 0.26 to 96.59); B vs. D: RR 3.83 (95% CI 0.20 to 73.00); C vs. D RR 0.76 (95% CI 0.02 to 36.04)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Klenerman, 1984	2 months	A vs. B vs. C vs. D: 15% (11/74) excluded from analysis, including 1 lost to followup	Appears complete	Not reported	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Koh, 2013	RCT	Korea Single center Pain clinic	Age ≥20 years, chronic lumbosacral radiculopathy secondary to spinal stenosis lasting ≥12 weeks, dominant leg pain with less severe back pain, unilateral leg pain with symptoms restricted to 1-level of dermatome, and previous failure of conservative management including physiotherapy, exercise therapy, analgesic medication, and acupuncture; MRI findings of lateral canal spinal stenosis (including lateral recess and foraminal spinal stenosis)	Unbearable pain >9 on the NRS, pain <4 NRS, acute back or leg pain, patients who had developed signs of progressive motor weakness or neurologic deficits, patients with a history of prior spinal surgery, allergies to steroids or contrast dyes, coagulopathy, injection of steroids or hyaluronic acids within the previous 12 weeks, systemic infections, injection site infections, unstable medical or psychiatric condition; bilateral radiculopathy, spondylolisthesis, multilevel spinal stenosis, and radiographic confirmed severe central canal stenosis	Approached: 259 Eligible: 86 Randomized: 68 (34 vs. 34) Analyzed: 53 (27 vs. 53) at 3 m, 25 (13 vs. 12) at 6 m	A: Transforaminal epidural steroid injection with 20 mg triamcinolone acetonide plus 2 mL 10% hypertonic saline (sodium chloride solution) (n=27) B: Transforaminal epidural steroid injection with 20 mg triamcinolone acetonide plus 2 mL 0.9% normal saline (n=26)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Koh, 2013	A vs. B: Age (mean): 66 vs. 63.7 years Male: 30% vs. 27% Duration of symptoms (months): 18.3 vs. 22.3 Baseline NRS (0-10): 7.26 vs. 6.60 Baseline ODI (1-100): 42.6 vs. 37.5	A vs. B Treatments prior to intervention: Prior epidural steroid injections 2.41 vs. 2.35 Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Not reported Provider experience: Anesthesiologist with 10 year career in pain medicine	Fluoroscopic guidance	Transforaminal epidural injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Koh, 2013	A vs. B <u>Pain</u> NRS (0-10): At baseline 7.26 vs. 6.60. Difference at 1 month -3.13 vs. -2.56 (p=0.25), at 2 months -3.22 vs. -1.94 (p=0.02), at 3 months -2.93 vs. -1.52 (p=0.01), at 4 months -2.78 vs. -1.50 (p=0.05), at 6 months -2.15 vs. -0.58 (p=0.17) <u>Global assessment</u> GPE mean values (1-7 Likert scale where 7=best ever and 1=worst ever). Difference at 1 month 5.82 vs. 5.65 (p=0.24), at 3 months 5.41 vs. 4.73 (p=0.02), at 6 months 4.59 vs. 4.22 (p=0.40) <u>Function</u> ODI, Korean version (0-100). At baseline 42.6 vs. 37.5. Difference at 1 month -13.22 vs. -10.08 (p=0.56), at 2 months -13.81 vs. -10.31 (p=0.45), at 3 months -12.70 vs. -8.08 (p=0.34), at 4 months -12.22 vs. -6.90 (p=0.41), at 6 months -6.85 vs. -3.83 (p=0.34)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Koh, 2013	6 months	A vs. B At 4 months 32% (11/34) vs. 41% (14/34), at 6 months 62% (21/34) vs. 65% (22/34)	Appears complete	1 withdrawal due to severe burning in the hypertonic saline group that resolved within 2 hours; no other reports of serious complications during injection and no other withdrawals due to adverse effects	None	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Kolsi, 2000	RCT	France Single center Rheumatology clinic	18 to 75 years of age; sciatica (L5 or S1) or femoral neuralgia (L4) with pain radiating at least to knee; positive straight leg raise or crossed straight leg raise; duration ≥15 days; baseline pain >5 on 0-10 scale; impingement of disc on nerve root by CT or MRI	Cauda equina syndrome; motor strength ≤2 on 0 to 5 scale; history of disc surgery or chemonucleolysis; epidural corticosteroid injection within 1 week; bleeding disorder or anticoagulant therapy; pregnant or breast-feeding; current infection; psychiatric disorders	Approached: Not reported Eligible: Not reported Randomized: 30 (17 vs. 13) Analyzed: 30 at 4 weeks	A: Transforaminal nerve root injection with 3.75 mg cortivazol (1.5 ml) plus 0.10 g lidocaine (2 ml), with fluoroscopic guidance (n=17) B: Interlaminar epidural injection with 3.75 mg cortivazol (1.5 ml) plus 0.10 g lidocaine (2 ml), with fluoroscopic guidance (n=13)
Kraemer, 1997, study 1	RCT	Germany Single center Clinical setting unclear	Inpatients with intractable unilateral sciatica extending below knee with paresthesia; positive SLR test; limited trunk movement and aggravation of pain by certain movements and coughing; disk protrusion with nerve root compression seen on MRI and/or CT; duration not specified	Presence of other concomitant disease like osteoporosis or diabetes; contraindications to steroids	Approached: Not reported Eligible: Not reported Randomized: 133 (47 vs. 40 vs. 46) Analyzed: 133 (includes patients with missing data, number unclear)	A: Epidural perineural injection via oblique interlaminar approach with 10 mg triamcinolone + local anesthetic (1 ml, drug not specified) (n=47) B: Interlaminar epidural steroid injection using conventional technique (medications and doses not reported) (n=40) C: Paravertebral local anesthetic injection (medications and doses not reported) (n=46)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Kolsi, 2000	A vs. B: Age (mean): 45 vs. 40 years Male: 41% vs. 38% Duration of symptoms (months): 3.7 vs. 4.4 Baseline leg pain (0-10 VAS): 7.0 vs. 6.3 Baseline back pain (0-10 VAS): 3.9 vs. 4.2 Baseline RDQ (French version) (0-24): 16 vs. 15	A vs. B: Treatment prior to intervention: Not specified Treatments following intervention: Not specified L5: 6/17 vs. 5/13 S1: 10/17 vs. 8/13 Intra- or extraforaminal nerve root impingement: 1/17 vs. 2/13 Midline herniation: 5/17 vs. 3/13 Herniation on side of pain: 11/17 vs. 7/13 Work-related injury: 24% (4/17) vs. 15% (2/13)	Number and frequency of injections: Number of injections not reported; open-label transforaminal nerve root steroid injection performed if <50% pain score decrease after first injection Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification	Head-to-head comparison of transforaminal vs. interlaminar steroid injection
Kraemer, 1997, study 1	A vs. B vs. C: Age (mean): Not reported Male: Not reported Duration of symptoms: Not reported Baseline pain: Not reported (Age, sex, duration of symptoms, baseline pain not reported by treatment group though reports no statistically significant difference) Function: Not reported	A vs. B vs. C: Treatments prior to intervention: Physiotherapy; back school; and dynamic flexion orthosis Other patient characteristics: Not reported	Number and frequency of injections: Single injection given three times in one week Number of levels: Single level Provider experience: Not reported	Not used routinely	Interlaminar epidural steroid injection (unclear if local anesthetic used) Soft tissue injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Kolsi, 2000	A vs. B: <u>Pain</u> Radicular pain (0-10 VAS, estimated from graph): at 2 weeks 7.0 vs. 6.3 at baseline, 2.6 vs. 1.6; at 4 weeks 2.0 vs. 1.5 Radicular pain, percent improvement from baseline (estimated from graph): at 1 week 78% vs. 73%; at 4 weeks 70% vs. 78% Back pain (0-10 VAS, estimated from graph): at baseline 3.9 vs. 4.2; at 2 weeks 1.5 vs. 2.4; at 4 weeks1.6 vs. 2.0 <u>Function</u> RDQ (French version, 0-24): at 4 weeks 16 vs.16 at baseline, 10 vs. 7.6 <u>Other outcomes</u> Underwent surgery: at 8 months 18% (3/17) vs. 23% (3/13) RR 0.76 (95% CI 0.18 vs. 3.20)
Kraemer, 1997, study 1	A vs. B vs. C: <u>Pain</u> *(Based on modified MacNab criteria; p-values not reported)* Modified MacNab criteria "good" (leg <10%, back pain <20%, return to work, sports as before; some results estimated from graph): 68% (32/47) vs. 53% (21/40) vs. 26% (12/46) at 3 months: A vs. B: 68% (32/47) vs. 53% (21/40), RR, 1.30 (95% CI 0.91 to 1.85); A vs. C: 68% (32/47) vs. 26% (12/46), RR 2.61 (95 % CI 1.55 to 4.41): B vs. C: 53% (21/40) vs. 26% (12/46), RR 2.02 (95% CI 1.14 to 3.55) <u>Other outcomes</u> Surgery: 8.5% (4/47) vs. 18% (7/40) vs. 13% (6/46) at 3 months; A vs. B: (4/47) vs. 18% (7/40), RR, 0.49 (5% CI 0.15 to 1.54); A vs. C: 8.5% (4/47) vs. 13% (6/46), RR 0.65 (95% CI 0.20 vs. 2.16); B vs. C: 18% (7/40) vs. 13% (6/46), RR 1.34 (95% CI 0.51 to 3.54)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Kolsi, 2000	4 weeks for pain, function; mean 8 months for surgery	None reported	Appears complete	A vs. B: 1 case of acute hypertension in group A	Not reported	Fair
Kraemer, 1997, study 1	3 months	Not reported by study or treatment arm; eight patients withdrew across two trials	Appears complete	No serious adverse events reported in any group. Headache: 1.9% (including group A in trial 2) vs. 3.6% vs. <1%	Not reported	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Kraemer, 1997, study 2	Study 2: A "prospective double-blind study," not described as randomized	Germany Single center University hospital setting, departments of Orthopaedic Surgery and Radiology	Inpatients with intractable unilateral sciatica extending below knee with paresthesia; positive SLR test; limited trunk movement and aggravation of pain by certain movements and coughing; disk protrusion with nerve root compression seen on MRI and/or CT; duration not specified	Presence of other concomitant disease like osteoporosis or diabetes; contraindications to steroids	Approached: Not reported Eligible: Not reported Randomized: 49 (24 vs. 25) Analyzed: 49 (includes patients with missing data, number unclear)	A: Epidural perineural injection via oblique interlaminar approach with 10 mg triamcinolone plus saline (volume not reported) (n=24) B: Epidural perineural injection via oblique interlaminar approach with saline alone plus intramuscular injection with 10 mg triamcinolone (n=25)
Laiq, 2009	RCT	Pakistan Single Center Setting unclear	Lumbar radicular pain (including low back and unilateral or bilateral leg pain); VAS pain score ≥6/10 for >2 weeks; single lumbar intervertebral disc herniation on recent MRI corresponding to clinical symptoms	Previous lumbar epidural steroid injections; previous lumbar spine surgery; unstable neurological deficits; cauda equina syndrome; radiologically proven facet syndrome; known contraindications for epidural steroid injections; infection; bleeding tendency or malignancy	Approached: Not reported Eligible: Not reported Randomized: 52 (26 vs. 26) Analyzed: 50 (25 vs. 25)	A: Interlaminar epidural injection with 80 mg methylprednisolone plus 2% Xylocaine (3 ml), preceded by 2% lidocaine (3 ml) (n=26) B: Ibuprofen 400 mg tid x 1 m, tramadol SR 100 mg QD x 2 m, tizanidine 2 mg bid x 3 m, famotidine 40 mg throughout treatment, bed rest and limited activity x 1 m with gradual increase to waling 2-3 h/day, heavy lifting and strenuous exercise not permitted for 3-6 m (n=25)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Kraemer, 1997, study 2	A vs. B: Age (mean): Not reported Male: Not reported Duration of symptoms: Not reported Baseline pain: Not reported (Age, sex, duration of symptoms, baseline pain not reported by treatment group though reports no statistically significant difference) Function: Not reported	A vs. B: Treatments prior to intervention: Physiotherapy; back school; and dynamic flexion orthosis Other patient characteristics: Not reported	Number and frequency of injections: Single injection given three times in one week; epidural perineural injection with corticosteroid performed if patients did not improve Number of levels: Single level Provider experience: Not reported	Not used routinely	Epidural perineural injection via oblique interlaminar approach with saline plus soft tissue injection with corticosteroid
Laiq, 2009	A vs. B: Age (mean): 40 vs. 41 years Male: 68% vs. 60% Duration of symptoms: Not reported Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatment prior to intervention: Not reported Treatments following intervention: Not reported Other patient characteristics: Not reported	Number and frequency of injections: Appears to be single injection Number of levels: Appears to be single level Provider experience: "Expert" (no other details provided)	Not reported	Non-injection therapy

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Kraemer, 1997, study 2	A vs. B: <u>Pain</u> Modified MacNab criteria "good" (leg <10%, back pain <20%, return to work, sports as before; estimated from graph): at 3 months 54% (13/24) vs. 40% (10/25), RR 1.35 (95% CI 0.74 to 2.48) <u>Other outcomes</u> Surgery: at 3 months 4% (1/24) vs. 4% (1/25), RR 1.04 (95% CI 0.07 to 15.73)
Laiq, 2009	A vs. B: Pain (0-10 VAS): 2 vs. 4 at 2 weeks, (p<0.0001); 2 vs. 4.5 at 1 month, (p<0.0001); 4.5 vs. 5.0 at 3 months, (p=0.19); 6 vs. 6.5 at 6 months, (p=0.21) Pain score >=6 (0-10 VAS): 16% (4/25) vs. 24% (6/25), RR 0.67 (95% CI 0.22 to 2.1) Patient satisfaction with improvement in pain: at 2 weeks 80% (20/25) vs. 52% (13/25), RR 1.54 (95 % CI 1.01 to 2.35) (p=0.38); at 1 month 76% (19/25) vs. 48% (12/25), RR 1.59 (95% CI 1.00 to 2.52) (p=0.36); at 3 months 52% (13/25) vs. 56% (14/25), RR 0.93 (95 % CI 0.56 to 1.55) (p=1.0); at 6 months 68% (17/25) vs. 64% (16/25), RR 106 (95% CI 0.71 to 1.58) (p = 1.0)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Kraemer, 1997, study 2	3 months	Not reported by study or treatment arm; eight patients withdrew overall across two trials	Appears complete	See Kraemer, 1997 above	Not reported	Fair
Laiq, 2009	6 months	A vs. B: 3.8% (1/26) vs. 3.8% (1/26)	Appears complete	A vs. B: "Major complications": 0% (0/25) vs. 0% (0/25) Blood glucose > 180 mg/dl) with no history of diabetes): 12% (3/25) vs. NR Flushing: 16% (4/25) vs. NR Headache:16% (4/25) vs. NR Backache: 4% (1/25) vs. NR	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Manchikanti, 2014 Manchikanti, 2013 Manchikanti, 2010	RCT	US Single center Pain clinic	≥ 18 years of age; disc herniation or radiculitis; function-limiting low back and lower extremity pain for ≥6 months; imaging findings not specified	Previous lumbar surgery; radiculitis secondary to spinal stenosis without disc herniation; uncontrollable or unstable opioid use; uncontrolled psychiatric disorder or acute/chronic medical illness; pregnant or lactating; patients with history, potential for adverse reaction to study medications	Approached: 162 Eligible: 140 Randomized: 120 (60 vs. 60) Analyzed: 120 at 2 years, including 19 (10 vs. 9) with missing data	A: Interlaminar epidural injection with 6 mg betamethasone (1 ml) plus 0.5% lidocaine (5 ml), with fluoroscopic guidance (n=60) B: Interlaminar epidural injection with 0.5% lidocaine (6 ml), with fluoroscopic guidance (n=60)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Manchikanti, 2014 Manchikanti, 2013 Manchikanti, 2010	A vs. B: Age (mean): 41 vs. 49 years Male: 62% vs. 38% Duration of symptoms (months): 133 vs. 135 Baseline pain (0 to 10 NRS): 8.0 vs. 8.2 Baseline ODI (0-50): 30 vs. 30	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified L4/5: 13% vs. 3.3% L5/S1: 87% vs. 95% Other patient characteristics: Not reported	Number and frequency of injections: Mean 6.1 vs. 5.3 over 2 years, frequency not specified Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification in epidural space	Interlaminar epidural injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Manchikanti, 2014 Manchikanti, 2013 Manchikanti, 2010	A vs. B: <u>Pain</u> Pain scores (0-10): at baseline 8.0 vs. 8.2; at 3 months 3.5 vs. 3.9; at 6 months 3.5 vs. 4.1; at 12 months 3.4 vs. 4.0; at 24 months 3.7 vs. 4.1 (p>0.05 at all time points) Pain relief >=50%: at 3 months 88% (53/60) vs. 78% (47/60), RR 1.13 (95% CI 0.96 to 1.33); at 6 months 88% (53/60) vs. 70% (42/60), RR 1.26 (95% CI 1.04 to 1.53); at 12 months 85% (51/60) vs. 72% (43/60), RR 1.19 (95% CI 0.98 to 1.44); at 24 months 70% (42/60) vs. 63% (38/60), RR 1.11 (95% CI 0.86 to 1.42) <u>Function</u> ODI (0-50): at baseline 30 vs. 30, at 3 months 14 vs. 16; at 6 months 14 vs. 16; at 12 months 13 vs. 16; at 24 months 14 vs. 16 (p>0.05 at all time points) ODI improved >=50%: at 3 months 82% (49/60) vs. 73% (44/60), RR 1.11 (95% CI 0.92 to 1.35); at 6 months 87% (52/60) vs. 63% (38/60), RR 1.37 (95% CI 1.10 to 1.70); at 12 months 87% (52/60) vs. 68% (41/60), RR 1.27 (95% CI 1.04 to 1.55); at 24 months 73% (44/60) vs. 63% (38/60), RR 1.16 (95% CI 0.91 to 1.48) <u>Other outcomes</u> Opioid use (mg MED/day): at baseline 47 vs. 50; at 3 months 42 vs. 34; at 6 months 36 vs. 37; at 12 months 36 vs. 37; at 24 months 37 vs. 36 (p>0.05 at all time points)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Manchikanti, 2014 Manchikanti, 2013 Manchikanti, 2010	24 months	A vs. B: 17% (10/60) vs. 15% (9/60) at 24 months	Appears complete	One dural puncture (treatment group not reported); no other major adverse events	Not reported	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Manchikanti, 2012 Manchikanti, 2011 Manchikanti, 2008	RCT	US Single center Pain clinic	Demonstrated disc herniation with radiculitis; >18 years of age; function-limiting low back and lower extremity pain for >6 months; imaging findings not specified	Previous lumbar surgery; radiculitis secondary to spinal stenosis or without disc herniation; uncontrollable or unstable opioid use; uncontrolled psychiatric disorders; uncontrolled medical illness; any conditions that could interfere with the interpretation of the outcome assessments; pregnant or lactating; history or potential for adverse reactions to local anesthetics or steroids	Approached: 178 Eligible: 132 Randomized: 120 (60 vs. 60) Analyzed: 120 (60 vs. 60) at 24 months, including 24 (12 vs. 12) with missing data	A: Caudal epidural injection with 6 mg betamethasone or 40 mg methylprednisolone plus 0.5% lidocaine (9 ml), with fluoroscopic guidance (n=60) B: Caudal epidural injection with 0.5% lidocaine (10 ml), with fluoroscopic guidance (n=60)
Matthews, 1987	RCT	UK Single center Specialty clinic	18 to 60 years of age; onset of most within 3 months; low back pain with asymmetrical restriction of lumbar spine movement; positive straight leg raise test and/or femoral nerve stretch test positive; radicular pain and uniradicular neurologic deficit; radiographs performed (imaging findings not specified)	Abnormalities or complicating problems after screening examination and investigations	Approached: 895 for 4 different trials (1 trial evaluated epidural injection) Eligible: Not reported Randomized: 57 (23 vs. 24) in trial of epidural injection Analyzed: 57 (23 vs. 34) at up to 12 months, including 3 (2 vs. 1) with missing data	A: Caudal epidural injection with 80 mg methylprednisolone (2 ml) and 0.125% bupivacaine (20 ml) (n=23) B: Soft tissue injection at sacral hiatus or tender point with lignocaine (2 ml, concentration not reported) (n=34)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Manchikanti, 2012 Manchikanti, 2011 Manchikanti, 2008	A vs. B: Age (mean): 43 vs. 49 years Male: 38% vs. 32% Duration of pain (months): 81 vs. 93 Baseline pain (0-10 NRS): 7.8 vs. 8.1 Baseline ODI (0 to 50): 28 vs. 29	A vs. B: Treatments prior to intervention: Not reported Treatments following intervention: Not reported Herniation level L3/4: 5% vs. 8% L4/L5: 70% vs. 67% L5/S1: 50% vs. 58% Other patient characteristics: Not reported	Number of injections: Mean 5.3 over 5.5 years, frequency not specified Number of levels: Caudal Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space	Caudal epidural injection with local anesthetic
Matthews, 1987	A vs. B: Age (median): 38 vs. 41 years Male: 83% vs. 71% Duration of symptoms (median, weeks): 4 vs. 4 weeks Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Acetaminophen as needed, opioid available on request; offered spinal corset and given instruction in 'posture' and 'back care' Other patient characteristics: Not reported	Number and frequency of injections: Injection repeated every 2 weeks, up to 3 times as needed Number of levels: Single level Provider experience: Not reported	Not reported	Soft tissue injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Manchikanti, 2012 Manchikanti, 2011 Manchikanti, 2008	A vs. B: <u>Pain</u> Pain (mean NRS, 0 to 10): at baseline 7.8 vs. 8.1; at 3 months 3.4 vs. 4.1; at 6 months 3.5 vs. 3.9; at 12 months 3.5 vs. 4.1; at 24 months 3.6 vs. 4.2: (p=0.80 for group difference) Pain improved >=50% from baseline: at 3 months 80% (48/60) vs. 77% (46/60); at 6 months 82% (49/60) vs. 77% (46/60); at 12 months 77% (46/60) vs. 70% (42/60); at 24 months 68% (41/60) vs. 63% (38/60) <u>Function</u> ODI (0 to 50): at baseline 28 vs. 29; at 3 months 14 vs. 16; at 6 months 14 vs. 16; at 12 months 13 vs. 16; at 24 months 14 vs. 16: (p=0.71 for group difference) ODI improved >=50% from baseline: at 3 months 73% (44/60) vs. 62% (37/60); at 6 months 73% (44/60) vs. 72% (43/60), RR 1.02 (95% CI 0.82 vs. 1.28); at 12 months 72% (43/60) vs. 67% (40/60), RR 108 (95% CI 0.85 to 1.37); at 24 months 70% (42/60) vs. 60% (36/60), RR 1.08 (95% CI 0.82 to 1.43) <u>Other outcomes</u> Opioid use (mg MED/day): at baseline 45 vs. 52; at 3 months 30 vs. 33; at 6 months 31 vs. 33; at 12 months 31 vs. 33; at 24 months 31 vs. 33: (p=0.75 for group difference) Success (pain improved >=50% and ODI improved >=50%): at 6 months 73% (44/60) vs. 72% (43/60); at 12 months 72% (43/60) vs. 67% (40/60); at 24 months 65% (39/60) vs. 60% (36/60)
Matthews, 1987	A vs. B: <u>Pain</u> Pain score (6 point NRS): at 1 month 67% (14/21) vs. 56% (18/32), RR 1.67 (95% CI 1.23 to 2.28) (p>0.05); No further pain: at 1 year 39% (9/23) vs. 41% (14/34), RR 0.95 (95% CI 0.49 to 1.8) <u>Other outcomes</u> Spinal surgery: 4% (1/23) vs. 0% (0/34), RR 4.38 (95% CI 0.19 to 102.94)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Manchikanti, 2012 Manchikanti, 2011 Manchikanti, 2008	24 months	A vs. B: 20% (12/60) vs. 20% (12/60) at 24 months	Appears complete	No major adverse events	Not reported	Fair
Matthews, 1987	Up to 1 year	A vs. B: 8.7% (2/23) vs. 2.9% (1/34) at 1 year	Appears complete	Not reported	Department of Health and Social Security (UK) and St. Thomas' Hospital, London	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
McCahon, 2011	RCT with crossover design	UK Single center Anesthesiology clinic	Back and leg pain of any cause; ≥2 epidural steroid injections in the last 12 months; ODI score >20%; back or leg VAS >30 mm	Anticoagulant therapy; bleeding diathesis; sepsis	Approached: 83 Eligible: 78 Randomized: 38 (19 vs. 19) Analyzed: 33 at 12 weeks following crossover intervention	A: Caudal epidural injection with 80 mg methylprednisolone acetate (2 ml), 0.25% levobupivacaine (10 ml), and saline (8 ml) (n=19) B: Caudal epidural injection with 40 mg methylprednisolone acetate (1 ml), 0.25% levobupivacaine (10 ml), and saline (9 ml) (n=19)
Murakibhavi, 2011	RCT	India Single center Orthopedic clinic	≥18 years of age; low back pain with unilateral or bilateral sciatica for ≥3 months; not responding to rest and analgesics; MRI showed lumbar disc disease (disc degeneration or herniation)	History of surgery; severe motor weakness; rapidly progressive neurological deficit; cauda equina syndrome; neurogenic claudication; local infection at injection site; steroid use in last 3 weeks; allergy to steroids; bleeding diathesis; pregnant; uncontrolled hypertension; uncontrolled diabetes	Approached: 189 Eligible: 189 Randomized: 102 (52 vs. 50) Analyzed: 100 (50 vs. 50) at 6 months	A: Caudal epidural injection with 80 mg triamcinolone acetate (2 ml), 2% lidocaine (2 ml), and normal saline (20 ml), with fluoroscopic guidance B: Conservative treatment (tizanidine 6-12 mg/d, diclofenac 50-100 mg/d, amitriptyline 10-50 mg qhs, bilateral skin traction, physiotherapy including TENS, short-wave diathermy, back extension exercises)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
McCahon, 2011	A vs. B: Age (mean): 56 years Male: 39% Duration of pain (years): 19 Baseline leg pain (0-100 VAS): 57 vs. 54 Baseline back pain (0-100 VAS): 67 vs. 66 Baseline ODI (0-100): 55 vs. 54	A vs. B: Treatments prior to intervention: ≥2 epidural injections in last 12 months (median 3 prior injections in last 12 months) Treatment following intervention: Not reported Other patient characteristics: Not reported	Number and frequency of injections: Appears to be single Number of levels: Caudal Provider experience: Not reported	None	Head-to-head comparison of different corticosteroid doses
Murakibhavi, 2011	A vs. B: Age (mean): 45 years (overall) Male: 66% (overall) Race: Not reported Duration of symptoms (months): 21 (overall) Baseline pain (0-10 VAS): 8.1 vs. 8.1 Baseline ODI (0-100): 36 vs. 36	A vs. B: Treatment prior to intervention: 98% rest/analgesics; 78% traction; 76% lumbar belt; 76% physiotherapy; 18% epidural injection Treatments following intervention: Not specified MRI findings: 60% disc degeneration; 26% disc bulge; 14% disc herniation	Number and frequency of injections: Repeat injection permitted after 2-3 weeks if <20% improvement in VAS pain; 12% received repeat injection Number of levels: Caudal injection Provider experience: Not reported	Fluoroscopic guidance without contrast verification	Conservative therapy

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
McCahon, 2011	A vs. B: <u>Function</u> Change in ODI from baseline (0-100, estimated from graph): -7 vs. -7 at 4 weeks; 0.5 vs. -3 at 8 weeks; 1 vs. 0 at 12 weeks <u>Other outcomes</u> Analgesic use: No difference between groups
Murakibhavi, 2011	A vs. B: <u>Pain</u> Pain (0-10 VAS): 8.1 vs. 8.1 at baseline; 2.7 vs. 6.1 at 6 months <u>Function</u> ODI (0-100): 36 vs. 36 at baseline; 12 vs. 25 at 6 months Beck Depression Inventory (0-63): 18 vs. 19 at baseline; 8.6 vs. 13 at 6 months <u>Other outcomes</u> Complete pain relief (complete, partial, no relief): 92% (46/50) vs. 32% (16/50) at 3 weeks, RR 2.88 (95 % CI 1.90 to 4.34); 86% (43/50) vs. 24% (12/50) at 6 months, RR 3.58 (95% CI 2.16 to 5.94)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
McCahon, 2011	12 weeks	A vs. B: 13% (5/38) withdrew, did not maintain ODI booklet, or did not return diary	Appears complete	"No adverse events reported"	No external funding	Fair
Murakibhavi, 2011	6 months	Not reported	3.8% (2/52) excluded in group A due to hypotension during procedure	A vs. B: Dural puncture: 0% (0/50) Headache: 18% (9/50) Hypotension during procedure: 24% (12/50) Bleeding during procedure: 4% (2/50)	NIH/NIAMS and University of Washington (through gift from Synthes Spine)	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Owlia, 2007	RCT	Iran Single center Rheumatology clinic	Lumbar radicular pain for >2 weeks; MRI showing disc herniation with or without canal stenosis; refractory pain despite NSAIDS; opioids, and physical therapy for >2 weeks	Prior back surgery; radiologically proven facet syndrome; signs or symptoms of infection; bleeding tendency; or malignancy	Approached: Not reported Eligible: Not reported Randomized: 84 (43 vs. 41) Analyzed: 84 at 3 months	A: Interlaminar epidural injection with 80 mg methylprednisolone acetate (8-10 ml) plus 2% lidocaine (2-4 ml), with fluoroscopic guidance (n=43) B: Interlaminar epidural injection with 40 mg methylprednisolone acetate (8-10 ml) plus 2% lidocaine (2-4 ml), with fluoroscopic guidance (n=41)
Park, 2010	RCT	South Korea Single center Neurosurgery clinic	18 to 80 years of age, lumbar radicular pain; MRI showing nerve root compromise; duration not specified	Chronic use of oral steroids; oral, peripheral, or epidural steroid use in past 3 months; temperature >100.4 F; pregnant; cognitive impairment; use of aspirin, Plavix, Coumadin, or heparin in last 2 weeks; history of bleeding disorders; history of lumbar surgery	Approached: Not reported Eligible: Not reported Randomized: 106 (53 vs. 53) Analyzed: 106 at 4 weeks	A: Transforaminal injection with 7.5 mg dexamethasone plus 1% lidocaine (1 ml), with fluoroscopic guidance (n=53) B: Transforaminal injection with 40 mg triamcinolone acetonide plus 1% lidocaine (1 ml), with fluoroscopic guidance (n=53)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Owlia, 2007	A vs. B: Age (mean): 38 vs. 36 years Male: 51% vs. 66% Duration of symptoms (weeks): 12 vs. 9 Baseline pain: Not reported Limitation in daily activities: 28% vs. 49%	A vs. B: Treatments prior to intervention: NSAIDS, opioids, and physical therapy for >2 weeks Treatments following intervention: Rehabilitative management for 2 weeks Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification in epidural space	Head-to-head comparison of alternative corticosteroid doses
Park, 2010	A vs. B: Age (mean): 56 vs. 62 years Male: 49% vs. 45% Duration of symptoms: Not reported Baseline pain (0-10 VAS): 7.5 vs. 8.3 Baseline ODI (0-100: 52 vs. 58	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified L4: 21% vs. 17% L5: 47% vs. 55% S1: 32% vs. 25%	Number and frequency of injections: Appears to be single injection Number of levels: Appears to be single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification	Head-to-head comparison of alternative corticosteroids

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Owlia, 2007	A vs. B: <u>Pain</u> Improvement in pain (not defined): at 2 weeks, 70% (30/43) vs. 61% (25/41), RR 1.14 (95% CI 0.84 to 1.57); at 1 month, 74% (32/43) vs. 76% (31/41), RR 0.98 (95% CI 0.77 to 1.25); at 3 months, 65% (28/43) vs. 51% (21/41), RR 1.27 (95% CI 0.88 to1.84)
Park, 2010	A vs. B: <u>Pain</u> Pain (0-10 VAS): 7.4 vs. 8.3 at baseline, 4.1 vs. 2.4 at 1 month ($p<0.0005$) McGill Pain Questionnaire summary score (0-45): 15 vs. 13 at baseline, 13 vs. 20 at 1 month ($p>0.05$) <u>Function</u> ODI (0-100): 52 vs. 58 at baseline, 45 vs. 59 at 1 month ($p>0.05$)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Owlia, 2007	3 months	None reported	Appears complete	A vs. B: Major complications: None Hyperglycemia: 4.6% (2/43) vs. 0% (0/41) Flushing: 14% (6/43) vs. 2.4% (1/41) Post-injection flare: 4.6% (2/43) vs. 7.3% (3/41) CSF hypotension: 2.3% (1/43) vs. 7.3% (3/41)	Not reported	Poor
Park, 2010	1 month	Not reported	Appears complete	Not reported	Wooridul Institute	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Park, 2013	RCT	Korea Single center Pain clinic	Back pain with pain radiating to leg; duration not specified; imaging confirmation not required	Systemic inflammatory disease; anticoagulant; uncontrolled diabetes; allergic reaction to lidocaine or contrast media; suspected or diagnosed infection; poor general health; skin defects in the injection area; psychiatric problems preventing the completion of a questionnaire; injections within 3 months; pain-relieving anti-inflammatory medication other than acetaminophen; undergoing physical therapy during the study period that might impact treatment effects; cauda equina syndrome; additional peripheral injections; surgery	Approached: 156 Eligible: 144 Randomized: 120 (60 vs. 60) Analyzed: 110 (55 vs. 55) at 12 weeks	A: Caudal epidural injection with 10 mg dexamethasone (2 ml) plus 0.5% lidocaine (13 ml) and 5 ml of iodinated contrast, with Doppler ultrasound and fluoroscopy guidance B: Caudal epidural injection with 10mg dexamethasone (2 ml) plus 0.5% lidocaine (13 ml) with 5 ml of iodinated contrast, with fluoroscopic guidance

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Park, 2013	A vs. B Age (mean): 57 vs. 58 years Male: 29% vs. 44% Duration of symptoms (months): 6.6 vs. 7.0 Baseline pain (0-10 NRS): 6.4 vs. 6.4 Baseline ODI (0-100): 51 vs. 52	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Herniated lumbar disc: 42% vs. 34% Spinal stenosis: 58% vs. 66% Target root L4: 36% vs. 36% Target root L5: 44% vs. 44% Target root S1: 9.1% vs. 20%	Number and frequency of injections: 51% vs. 53% received 2 injections within 2 week interval; 2nd injection performed if <50% reduction in pain NRS after 1st injection Number of levels: Caudal Provider experience: Not reported	Doppler ultrasound with contrast verification in epidural space, also fluoroscopic confirmation vs. fluoroscopy with contrast verification in epidural space (without ultrasound)	Head-to-head comparison of alternative imaging guidance methods

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Park, 2013	A vs. B: <u>Pain</u> Pain (0-10 NRS): 6.4 vs. 6.4 at baseline; 3.1 vs. 3.2 at 2 weeks; 2.5 vs. 2.6 at 12 weeks, (p>0.05) <u>Function</u> ODI (0-100): 51 vs. 52 at baseline; 33 vs. 31 at 2 weeks; 29 vs. 29 at 12 weeks, (p>0.05) <u>Global assessment</u> Pain score improvement >50% and ODI improvement >40%: at 2 weeks 87% (48/55) vs. 89% (49/55), RR 0.98 (95% CI 0.85 to 1.12); at 12 weeks 76% (42/55) vs. 74% (41/55), RR 1.02 (95% CI 0.83 to 1.27)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Park, 2013	12 weeks	None reported	6 (4 vs. 2) discontinued interventions due to lack of response or worsening of pain, 4 excluded due to peripheral injections or use of non-permitted medications	A vs. B: Vasovagal reaction: 3.6% (2/55) vs. 5.4% (3/55) Headache: 3.6% (2/55) vs. 1.8% (1/55) Pain exacerbation: 9.1% (5/55) vs. 7.3% (4/55) Post lumbar puncture syndrome: None Infection or hematoma: None Intravascular injection: 0% (0/55) vs. 3.6% (2/55)	Inje University, South Korea	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Rados, 2011	RCT	Croatia Single center Pain clinic	Unilateral lumbosacral radicular leg pain greater than back pain; duration <1 year; unresponsive to ≥6 weeks of conservative management; pain score ≥5; underwent MRI and EMG	Motor or bowel/bladder impairment; lumbar canal stenosis on MRI or x-ray that could explain symptoms; pregnant; allergic to steroids; bleeding history; infections; on anticoagulants; neurological deficits secondary to spine pathology; previous lumbar spinal surgery; previous caudal or lumbar epidural steroid injection; history of opioid abuse or currently on long acting opioids	Approached: Not reported Eligible: Not reported Randomized: 70 (35 vs. 35) Analyzed: 64 (32 vs. 32) at 24 weeks	A: Transforaminal epidural injection with 40 mg methylprednisolone plus 0.5% lidocaine (3 ml), with fluoroscopic guidance B: Interlaminar epidural injection with 80 mf methylprednisolone plus 0.5% lidocaine (8 ml), with fluoroscopic guidance
Ridley, 1988	RCT	UK Single center Rheumatology clinic	Clinical history consistent with sciatic nerve root compression with numbness or paresthesia or objective neurologic deficit	Prior epidural injection; spinal surgery	Approached: Not reported Eligible: Not reported Randomized: 39 Analyzed: 35 (19 vs. 15) at 2 weeks	A: Interlaminar epidural injection with 80 mg methylprednisolone (2 ml) and saline (10 ml) (n=19) B: Interspinous ligament injection with saline (2 ml) (n=16)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Rados, 2011	A vs. B: Age (mean): 49 vs. 49 years Male: 62% vs. 66% Duration of symptoms: Not reported (<1 year and >6 weeks by inclusion criteria) Baseline pain (0-10 VAS): 6.7 vs. 7.4 Baseline ODI (0-100): 53 vs. 52	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: tramadol 50 mg 1-2 T po q 6 h prn L4-5: 43% vs. 41% L5-S1: 57% vs. 59% Other patient characteristics: Not reported	Number and frequency of injections: 3 injections at 2 week intervals Number of levels: Single level Provider experience: Not reported	Fluoroscopic guidance with contrast verification	Head-to-head comparison of transforaminal vs. interlaminar steroid injection
Ridley, 1988	A vs. B: Age (mean): 40 vs. 39 years Male: 42% vs. 44% Duration of symptoms >6 months: 47% vs. 56% Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection repeated after 1 week if no improvement Number of levels: Single level Provider experience: Not reported	Not reported	Non-epidural saline injection

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Rados, 2011	A vs. B: <u>Pain</u> Pain (0-10 VAS, estimated from graph): at baseline 6.7 vs. 7.4; at 2 weeks, 5.0 vs. 5.0; at 4 weeks, 4.2 vs. 4.0; 12 weeks, 3.8 vs. 4.0 Pain improved >=2 (0-10 VAS): 84% (27/32) vs. 75% (24/32): RR, 1.13 (95% CI 0.88 to 1.44) Pain improved >50%: 63% (20/32) vs. 53% (17/32) at 24 weeks: RR, 1.18 (95% CI 0.77 to 1.79) <u>Function</u> ODI (0-100, estimated from graph): at baseline, 53 vs. 52; at 2 weeks, 47 vs. 47; at 4 weeks, 46 vs. 44; at 12 weeks, 42 vs. 42; at 24 weeks, 39 vs. 40 ODI improved >10 points: 66% (21/32) vs. 50% (16/32), RR, 1.31 (95% CI 0.86 to 2.01)
Ridley, 1988	A vs. B: <u>Pain</u> Rest pain, improvement from baseline (median, 0-10 VAS): at 2 weeks 46% vs. 0%, ($p<0.01$) Walking pain, improvement from baseline (median, 0-10 VAS): at 2 weeks 69% vs. 0%, ($p<0.01$)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Rados, 2011	24 weeks	A vs. B: 8.6% (3/5) vs. 8.6% (3/35) at 6 months (excluded because they did not undergo 3 injections)	Appears complete	Not reported	No external funding	Fair
Ridley, 1988	2 weeks	A vs. B: 5% (2/39) at 2 weeks	14 crossovers in placebo group; timing unclear	None reported	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Riew, 2000 Riew, 2006	RCT	USA Single center Spine surgery clinic	>21 years of age; degenerative lumbar radicular pain with disc herniation or spinal stenosis confirmed by MRI or CT; completed course of nonoperative management (NSAID, PT, activity modification) for at least 6 weeks without adequate benefit, unless in intractable pain despite maximum NSAID plus opioid; surgery considered appropriate	Acute trauma; cauda equina syndrome; progressive neurological deficit; motor deficit; pathologic or infectious etiology; not an operative candidate; Workers' Compensation claim; history of an adverse reaction to corticosteroids or local anesthetics; lack of a radiographically detectable abnormality; more than two radiographically abnormal and symptomatic levels on either side; absence of substantial radicular pain as the presenting symptom	Approached: Not reported Eligible: Not reported Randomized: 55 (28 vs. 27) Analyzed: 55 at 13-28 months, 55 at >5 years, including 8 (8 vs. 0) with missing data	A: Transforaminal nerve root injection with 6 mg betamethasone (1 ml) plus 0.25% bupivacaine (1 ml), with fluoroscopic guidance (n=28) B: Transforaminal nerve root injection with 0.25% bupivacaine (1 ml), with fluoroscopic guidance (n=27)
Rogers 1992	RCT	UK Single center Pain clinic	Clinical diagnosis of sciatica with positive straight leg raise at less than 60 degrees; duration and imaging findings not specified	Not reported	Approached: Not reported Eligible: Not reported Randomized: 30 (15 vs. 15) Analyzed: 30 Lost to followup: Not reported	A: Interlaminar epidural injection with 80 mg methylprednisolone (2 ml) plus 2% lignocaine (14 ml) plus saline (4 ml) (n=15) B: Interlaminar epidural injection with 2% lignocaine (14 ml) + saline (6 ml) (n=15)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Riew, 2000 Riew, 2006	A vs. B: Age: Not reported (states no difference) Male: 49% overall (states no difference) Duration of symptoms: Not reported Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: NSAIDs; PT; and activity modification for ≥6 weeks; +/- opioid Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection with 4 additional injections during followup period-19 had >1; frequency not specified (range 6 days to 10.5 months) Number of levels: One or two (determined by surgeon based on patient's history) Provider experience: Radiologists experienced in the injection technique	Fluoroscopic guidance with contrast verification of nerve root site	Transforaminal nerve root injection with local anesthetic
Rogers 1992	A vs. B: Age (mean): 42 vs. 41 years Male: 47% vs. 47% Duration of symptoms (months): 23 vs. 25 Baseline pain "severe" or "very severe": 87% vs. 67% Baseline function: Not reported	A vs. B: Treatments prior to intervention: Prior surgery: 1/15 vs. 0/15 Prior epidural injection: 4/15 vs. 2/15 Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Not reported	Not reported	Interlaminar epidural injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Riew, 2000 Riew, 2006	A vs. B: <u>Other outcomes</u> Underwent surgery: 29% (8/28) vs. 67% (18/27) at 13 to 28 months, RR 0.43 (95% CI 0.22 to 0.82); 39% (11/28) vs. 70% (19/27) at >=5 years, RR 0.56 (95% CI 0.33 to 0.94) (assuming none lost to follow-up had surgery); 68% (19/28) vs. 70% (19/27), RR 0.96 (95% CI 0.66 to 1.4) (assuming all lost to follow-up had surgery)
Rogers 1992	A vs. B: <u>Pain</u> Pain "none" (none, mild, moderate, severe): 20% (3/15) vs. 6.7% (1/15), RR 3.0 (95% CI 0.35 to 26) Pain "none" or "mild": 47% (7/15) vs. 20% (3/15), RR 2.33 (95% CI 0.74 to 7.35) <u>Function</u> Full ability to work: 53% (8/15) vs. 33% (5/15), RR 1.6 (95% CI 0.68 to 3.80) <u>Other outcomes</u> Reduced analgesic intake: 53% (8/15) vs. 40% (6/15, RR 1.33 (95% CI 0.61 to 2.9) Subsequent surgery: 27% (4/15) vs. 27% (4/15), RR 1.0 (95% CI 0.31 to 3.28)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Riew, 2000 Riew, 2006	Mean 23 months, range 13 to 28 months for initial followup; ≥5 years for second followup	A vs. B: None at 13 to 28 months; 29% (8/28) vs. 0% (0/27) at ≥5 years	Appears complete	Not reported	Barnes-Jewish Christian Health System's Innovations in Health Care Grant and Washington University School of Medicine	Fair
Rogers 1992	1 month for all outcomes except subsequent surgery, which was evaluated at 20-21 months	Not reported	Appears complete	Not reported	Not reported	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Sayegh, 2009	RCT	Greece Single center Orthopedic Department	Low back pain for ≥ 1 month with or without unilateral or bilateral sciatica; failure to respond to conservative measures; disc degeneration or herniation on MRI	Cauda equina or spinal stenosis; psychosomatic diseases or any other pathology	Approached: Not reported Eligible: 191 Randomized: 183 (93 vs. 90) Analyzed: 151 (81 vs. 70) at 1 year	A: Caudal epidural injection with betamethasone (2 mg/dL betamethasone dipropionate + 5 mg/dL betamethasone phosphate) (1 ml) + 2% Xylocaine (12 ml) (n=93) B: Caudal epidural injection with 2% Xylocaine (12 ml) + water for injection (8 ml) (n=90)
Snoek, 1977	RCT	Norway Single center Neurology and anesthesiology clinic	Radiating pain in the distribution of the sciatic or femoral nerve; neurologic deficit that correlated with compression of L4, L5, or S1 nerve root; myelographic findings at the appropriate level and side; duration not specified	Acute severe motor paresis; cauda equina syndrome; intolerable pain; previous lumbar spine surgery; contraindications to corticosteroids; doubts about myelography findings	Approached: >200 Eligible: Not reported Randomized: 51 (27 vs. 24) Analyzed: Unclear	A: Interlaminar epidural injection with 80 mg methylprednisolone (2 ml) (n=27) B: Interlaminar epidural injection with saline (2 ml) (n=24)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Sayegh, 2009	A vs. B: Age (mean): 51 vs. 48 years Male: 65% vs. 70% Duration of symptoms (days): 53 vs. 51 Baseline pain: Not reported Baseline ODI (0-100): 39 vs. 39	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Acetaminophen allowed during first 4 weeks of study, but not NSAIDs Other patient characteristics: Not reported	Number and frequency of injections: 51/183 (28%) received 2nd injection 1-2 weeks after 1st for failure to improve Number of levels: Caudal injection Provider experience: Not reported	No fluoroscopic guidance	Caudal epidural injection with local anesthetic
Snoek, 1977	A vs. B: Age (mean): 44 vs. 46 years Male: 48% vs. 54% Duration of symptoms (weeks): 12 vs. 11 Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Not reported	Not reported	Interlaminar epidural injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Sayegh, 2009	A vs. B: <u>Function</u> ODI (scale NR): 39 vs. 39 at baseline (p=0.75); 13 vs. 6.2 at 1 week (p<0.0005); 12 vs. 9.6 at 1 month (p<0.0005); 5.8 vs. 14 at 6 months (p<0.0005); 4.9 vs. 13 at 1 year (p<0.0005) <u>Other outcomes</u> Surgery (overall): 16% (13/83) vs. 22% (19/85) at 1 month, RR 0.70 (95% CI 0.37 to 1.3) Surgery (disc herniation group): 17% (7/42) vs. 24% (8/33) at 1 month, RR 0.69 (95% CI 0.28 to 1.70)
Snoek, 1977	A vs. B: <u>Other outcomes</u> Subsequent surgery: 52% (14/27) vs. 58% (14/24), RR 0.89 (95% CI 0.54 to 1.5)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Sayegh, 2009	1 year	A vs. B: 13% (12/93) vs. 22% (20/90) at 1 year	Appears complete	A vs. B: Transient lower extremity numbness: 13% (12/93) vs. 8.9% (8/90) "No patient reported any major immediate or late complications"	Not reported	Fair
Snoek, 1977	Mean not reported; range 8-20 months after injection	Not reported	Unclear	A few patients who felt increased pain of sciatic distribution	Not reported	Poor

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Tafazal, 2009; Ng, 2005	RCT	UK Single center Spine clinic	Unilateral leg pain with intensity comparable to back pain intensity; MRI diagnosis of lumbar disc herniation or foraminal stenosis; ≥ 6 weeks of failed conservative treatment	Acute back trauma; cauda equina syndrome; active local skin infection; previous back operation; periradicular infiltration during previous 12 months; epidural injection in last 3 months; pregnant; allergy to treatment agents; anticoagulation treatment	Approached: Not reported Eligible: Not reported Randomized: 150 (74 vs. 76) Analyzed: 124 (65 vs. 59) at 3 months)	A: Transforaminal periradicular injection with 40 mg methylprednisolone plus 0.25% bupivacaine (2 ml), with fluoroscopic guidance (n=74) B: Transforaminal periradicular injection with 0.25% bupivacaine (2 ml), with fluoroscopic guidance (n=76)
Tauheed, 2014	RCT	India Single center Pain clinic	Ages 18-55 years, weight between 40-70 kg, ASA grade I or II, suffering from sciatica due to disc herniation, and symptomatic for ≥6 weeks; 1 or 2 level disc herniation at L3-L4, L4-L5, L5-S1 on MRI	Large HNP with severe central or foraminal stenosis on MRI, progressive neurologic deficits, cauda-equina syndrome, blood coagulation disorder, valvular heart diseases, hypotension, emotional instability, known history of allergy to local anesthetics, corticosteroids or clonidine or received prior epidural steroid injection or lumbar surgery	Approached: Not reported Eligible: Not reported Randomized: 180 (60 vs. 60 vs. 60) Analyzed: 177 (60 vs. 58 vs. 59) at 12 w	A: Transforaminal sleeve root injection with 60 mg methylprednisolone (n=60) B: Transforaminal sleeve root injection with 60 mg methylprednisolone plus 0.5 mcg/kg clonidine (n=60) C: Transforaminal sleeve root injection with 60 mg methylprednisolone plus 1 mcg/kg clonidine (n=60)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Tafazal, 2009; Ng, 2005	A vs. B: Age (mean): 52 vs. 51 years Male: 60% vs. 54% Duration of symptoms (months): 20 vs. 18 months Baseline leg pain (0-100 VAS): 73 vs. 76 Baseline back pain (0-100 VAS): 44 vs. 48 Baseline ODI (0-100): 43 vs. 47	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 13% vs. 15% received subsequent injections, mean number not reported, frequency not specified Number of levels: Single level Provider experience: Senior surgeon	Fluoroscopy with contrast verification	Transforaminal periradicular injection with local anesthetic
Tauheed, 2014	A vs. B vs. C: Age (mean): 39 vs. 42 vs. 41 Male: 63% vs. 72% vs. 67% Duration of pain: 128 vs. 130 vs. 127 days	A vs. B vs. C: Treatments prior to intervention: Not specified Treatments following intervention: Not reported Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Two levels, depending upon the level of disc herniation Provider experience: Not reported	Fluoroscopic guidance	Transforaminal epidural injection with clonidine

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Tafazal, 2009; Ng, 2005	A vs. B: <u>Pain</u> Leg pain, change from baseline (mean, 0-100 VAS): 26 vs. 19 at 6 weeks, 24 vs. 23 at 12 weeks (p=0.74) Back pain, change from baseline (mean, 0-100 VAS): 9.8 vs. 6.4 at 6 weeks, 6.9 vs. 9.9 at 12 weeks (p=0.57) Leg pain improved >=20 points (0-100 VAS) (from Ng): at 12 weeks 42% (18/43) vs. 48% (20/43): RR, 0.90 (95% CI 0.56 to 1.50) <u>Function</u> ODI, change from baseline (mean, 0-100 VAS): 9.3 vs. 11 at 12 weeks (p=0.69) Low Back Outcome Score, change from baseline (mean, 0-75): 8.8 vs. 8.5 at 6 weeks, 9.1 vs. 9.4 at 12 weeks (p=0.93) ODI improved ≥ 10% (from Ng): at 12 weeks 35% (15/43) vs. 55% (24/43; RR 0.63 (95% CI 0.38 to 1.0) Change in walking distance from baseline (yards) (from Ng): at 6 weeks 89 vs. 220 (0.12); 200 vs. 240 at 12 weeks (p=0.72) <u>Global assessment</u> Satisfaction excellent or good (from Ng): at 12 weeks 45% (18/40) vs. 49% (20/4) RR, 0.92 (95% CI 0.58 to 1.5) <u>Other outcomes</u> Subsequent peri-radicular injection: 13% (8/64) vs. 15% (10/65) at 1 year, RR 0.81 (95% CI 0.34 to 1.93) Surgery a 12 weeks (from Ng): 2.5% (1/40) vs. 0% (0/41): RR, 3.07 (95% CI 0.13 to 73.28) (4 of 5 patients who withdrew at 6 weeks also had surgery, not reported by treatment arm) Surgery at 1 year: 14% (9/64) vs. 22% (14/65)], RR 0.65 (95% CI 0.30 to 1.40)
Tauheed, 2014	A vs. B vs. C: <u>Pain</u> Global pain score (VAS, 0-100): At baseline 7.83 vs. 7.60 vs. 7.72, at 1 week 5.41 vs. 4.62 vs. 4.41, at 2 weeks 3.97 vs. 3.61 vs. 2.02, at 4 weeks 4.37, 3.91 vs. 2.23, at 6 weeks 4.46 vs. 4.11 vs. 2.41, and 12 weeks 4.66 vs. 4.24 vs. 2.65 (p >0.05 at all followup)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Tafazal, 2009; Ng, 2005	12 weeks (pain and function); 1 year (need for surgery or additional interventions)	A vs. B: 14% (21/150)	Appears complete	2 deaths; not stratified by treatment group	Not reported	Fair
Tauheed, 2014	12 weeks	A vs. B vs. C: 0 vs. 1 vs. 0	Appears complete	No serious adverse events or complication rates reported in any group	Not reported	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Thomas, 2003	RCT	France Single center Rheumatology clinic	>18 years of age; radicular pain <3 months; disc herniation of L4-L5 or L5-S1 confirmed by CT or MRI; radicular pain intensity >30 on 0 to 100 VAS	Epidural corticosteroid injection within 1 month; history of spinal surgery; motor or sphincter dysfunction requiring emergency surgery; iodine allergy; anticoagulant intake; depression; employment disruption >6 months; occupational injury	Approached: Not reported Eligible: Not reported Randomized: 31 (15 vs. 16) Analyzed: 22 (10 vs. 12) at 6 months	A: Transforaminal injection with 5 mg dexamethasone acetate (2 ml), with fluoroscopic guidance (n=15) B: Interlaminar epidural injection with 5 mg dexamethasone acetate (2 ml), with fluoroscopic guidance (n=16)
Valat, 2003	RCT	France Single center Rheumatology clinic	First or recurrent episode of sciatica (pain in one leg, radiation below knee, at least one nerve root compression, sign); duration 15 to 180 days; pain >30 on 0-100 mm VAS	Requiring surgery; structural spinal deformities; symptoms from causes other than herniated disc; spinal injection in past month; prior low back surgery; chemonucleolysis; or nucleotomy; pregnant; allergy to corticosteroid; treated with tricyclic antidepressant or lithium; out of work >1 year; worker's compensation	Approached: Not reported Eligible: Not reported Randomized: 85 (43 vs. 42) Analyzed: 63 (33 vs. 30) at 35 days	A: Interlaminar epidural injection with 50 mg prednisolone acetate (2 ml) (n=43) B: Interlaminar epidural injection with saline (2 ml) (n=42)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Thomas, 2003	A vs. B: Age (mean): 50 vs. 51 years Male: 53% vs. 31% Duration of symptoms (weeks): 6.5 vs. 6.8 Baseline leg pain (0-100 VAS): 74 vs. 72 Baseline RDQ (0-24): 12 vs. 14	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Rest and physical therapy (not otherwise specified) Lateral (vs. posterior) herniation: 33% vs. 25% Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level (L4-5) Provider experience: Not reported	Fluoroscopic guidance with contrast verification of nerve root (transforaminal) or epidural space (interlaminar)	Head-to-head comparison of different approaches for epidural injections
Valat, 2003	A vs. B: Age (mean): 44 vs. 38 years Male: 60% vs. 62% Duration of symptoms (days): 15 vs. 17 Baseline pain (0-100 VAS): 58 vs. 58 Baseline RDQ (0-24): 15 vs. 14	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 3 injections at 2 day intervals Number of levels: Single Provider experience: Not reported	None reported	Interlaminar epidural injection with saline

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Thomas, 2003	A vs. B: Pain Leg pain (0-100 VAS): 74 vs. 72 at baseline; at 1 month 17 vs. 31(p=0.04); at 6 months 22 vs. 44 (p=0.04) Function RDQ (0-24): 12 vs. 14 at baseline; at 1 month, 7.9 vs. 9.6 (p>0.05); at 6 months, 5.3 vs.10 at (p=0.05) Dallas Daily Activities: 84 vs. 84 at baseline; at 1 month 52 vs. 59 (p>0.05); at 6 months, 46 vs. 69 (p=0.05) Dallas Work and Leisure Activities: at baseline 99 vs. 96, (p>0.05); at 6 months, 37 vs. 60 (p=0.02) Dallas Anxiety-Depression: at baseline 50 vs. 64; at 1 month 36 vs. 40, (p>0.05); at 6 months 34 vs. 55, (p=0.04) Dallas Sociability: at baseline 47 vs. 54; at 1 month 33 vs. 32, (p>0.05); at 6 months 30 vs. 44, (p>0.05) Other outcomes Surgery at 6 months:33% (5/15) vs. 25% (4/16), RR, 1.33 (95% CI 0.44 to 4.05)
Valat, 2003	A vs. B: Pain Pain (0-100 VAS): 58 vs. 58 at baseline; 28 vs. 40 at day 20, difference -11 (95% CI -23 to 1.3); 22 vs. 25 at day 35, difference -5.1 (95% CI -19 to 8.4) Success (recovery or marked improvement on four category scale and not requiring NSAID): 51% (22/43) vs. 36% (15/42), RR 1.43 (95% CI (p=0.15) at day 20; 49% (21/43) vs. 48% (20/42) at day 35, RR 1.03 (95% CI 0.66 to 1.59) Function RDQ (0-24): 15.1 vs. 14.2 at baseline; 10.9 vs. 11.7 at day 20, difference -1.8 (95% CI -4.6 to 1.0); 8.5 vs. 9.1 at day 35, difference -2.1 (95% CI -5.0 to 0.8) Dallas Daily Activities: 66 vs. 69 at baseline; 41 vs. 49 at day 20, difference -3 (95% CI -18 to 5.7), 31 vs. 40 at day 35, difference -5.7 (95% CI -18 to 7.1) Dallas Work and Leisure Activities: at baseline 73 vs. 78; 50 vs. 62 at day 20, difference -7.2 (95% CI -21 to 6.2); 41 vs. 47at day 35 , difference -7.3 (95% CI -22 to 7.1) Dallas Anxiety-Depression: 29 vs. 34 at baseline; 21 vs. 30 at day 20, difference -3.2 (95% CI -16 to 9.8); 16 vs. 26 at day 35, difference -5.3 (95% CI -19 to 8.4) Dallas Sociability: 29 vs. 25 at baseline; 18 vs. 20 at day 20, difference -10 (95% CI -20 to -0.9); 14 vs. 20 at day 35, difference -12 (95% CI -22 to -2.5) Other outcomes Surgery: 2.3% (1/43) vs. 4.7% (2/42), RR 0.49 (95% CI 0.05 to 5.19)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Thomas, 2003	6 months	A vs. B: None; 9 patients who underwent surgery excluded from 6 month analysis	Appears complete	Not reported	Not reported	Fair
Valat, 2003	35 days	A vs. B: 23% (10/43) vs. 29% (12/42) at 35 days	Appears complete	A vs. B: Headache: 9.3% (2/43) vs. 5% (2/40)	Ministry of Health	Fair

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental & control groups, dose, duration of treatment)
Wilson-MacDonald, 2005	RCT	UK Single center Surgery clinic	Lumbosacral nerve root pain >6 weeks of sufficient intensity to warrant surgery; MRI showing disc prolapse and/or spinal stenosis	Not a surgical candidate; cauda equina syndrome; deteriorating neurological function	Approached: Not reported Eligible: Not reported Randomized: 93 (44 vs. 48) Analyzed: 72 (36 vs. 36) at 3 months	A: Interlaminar epidural steroid injection with 80 mg methylprednisolone (2 ml) plus 40 mg 0.5% bupivacaine (8 ml) (n=44) B: Intramuscular/interspinous ligament injection with 80 mg methylprednisolone (2 ml) plus 40 mg 0.5% bupivacaine (8 ml) (n=48)
el Zahaar, 1991	RCT	Egypt Single center Surgery clinic	Acute unilateral sciatica with neurological findings or neurogenic claudication without specific neurologic deficits; failure to improve with at least 2 weeks of conservative therapy; findings on MRI or CT consistent with clinical presentation	Surgery for similar symptoms or within 6 months	Approached: Not reported Eligible: Not reported Randomized: 63 (37 vs. 26) Analyzed: Unclear	A: Caudal epidural injection with hydrocortisone (5 ml), 4% Carbocaine (4 ml), and saline (21 ml) (n=37) B: Caudal epidural injection with 4% Carbocaine (4 ml) plus saline (26 cc) (n=26)

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance	Type of Comparison
Wilson-MacDonald, 2005	A vs. B: Age (mean): 49 vs. 49 years Male: 40% (entire cohort) Herniated disc: 52% vs. 40% Spinal stenosis: 41% vs. 29% Both: 7% vs. 31% Duration of symptoms: Not reported (>6 weeks for all) Baseline pain: Not reported Baseline ODI (0-100): 44 vs. 40	A vs. B: Treatment prior to intervention: 16% (7/44) vs. 19% (9/48) previous epidural injection, chemonucleolysis, or surgery Treatment following intervention: Not specified Other patient characteristics: Not reported	Number and frequency of injections: 16% (7/44) vs. 19% (9/48) received a second epidural following the 6 week visit Number of levels: Appears to be single Provider experience: Not reported	Not reported	Nonepidural injection with corticosteroid plus local anesthetic
el Zahaar, 1991	A vs. B: Age (mean): 46 vs. 49 years Male: 54% vs. 65% Duration of symptoms (months): 17 vs. 14 Herniated disc: 51% vs. 54% Spinal stenosis: 49% vs. 46% Baseline pain: Not reported Baseline function: Not reported	A vs. B: Treatment prior to intervention: Not specified Treatment following intervention: Advised to take aspirin; no physical therapy or exercise program Other patient characteristics: Not reported	Number and frequency of injections: Single injection Number of levels: Single level Provider experience: Not reported	Not reported	Caudal epidural injection with local anesthetic

Appendix E1. Epidural Steroid Injections for Radiculopathy and Herniated Disc

Author, Year Title	Results
Wilson-MacDonald, 2005	A vs. B: <u>Pain</u> Pain relief: Favored intervention A (p<0.004), data not provided <u>Other outcomes</u> Underwent surgery: 41% (18/44) vs. 31% (15/48) at >=2 years, RR: 1.31 (95% CI 0.76 to 2.27)
el Zahaar, 1991	A vs. B: <u>Other outcomes</u> Treatment success (>75% improvement in pre-injection symptoms and no spinal surgery): 49% (18/37) vs.50% (13/26) at 13-36 months, RR 0.97 (95% CI 0.59 to 1.62); 58% (11/19) vs. 64% (9/14) in patients with herniated disc, RR 0.90 (95% CI 0.52 to 1.56) Subsequent surgery: 13/37 (35%) vs. 10/26 (38%) at 13-36 months, RR 0.91 (95% CI 0.47 to 1.76); 26% (5/19) vs. 21% (3/14) in patients with herniated disc, RR 1.23 (95% CI 0.35 to 4.30)

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Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating
Wilson-MacDonald, 2005	At least 2 years	Unclear	19% (9/19) in nonepidural injection group received epidural corticosteroid injection due to continued symptoms	Not reported	Not reported	Fair
el Zahaar, 1991	Mean 20 to 21 months	Unclear	Appears complete	Not reported	Not reported	Poor

ACS=acute coronary syndrome; BMI=body mass index; cc=cubic centimeters; CI=confidence interval; CT=computed tomography; DLG=poly(DL-lactide-co-glycolide); DLR=digital luminescence radiography; EMG=electromyography; ER=emergency room; ESI=epidural steroid injection; F=female; FABQ=Fear-Avoidance Beliefs Questionnaire; FL=fetal length; gD=growth and development; h=hours; HAD=healthcare alternatives development; IL=interlaminar; L=angular momentum; m=months; MED=minimal effective dose; MIL=midline interlaminar; MRI=magnetic resonance imaging; NIAMS=National Institute of Arthritis and Musculoskeletal and Skin Diseases; NIH=National Institutes of Health; NR=no results; OR=not reported; NRS=numeric rating scale; NS=not significant; NSAID=nonsteroidal antiinflammatory drug; ODI=Oswestry Disability Index; PIL=pre illness level; PLC=pityriasis lichenoides chronica; PT=physical therapy; RCT=randomized controlled trial; RDQ=Roland Disability Questionnaire; RR=relative risk; S=Diabetes; SF-36=Short Form (36) Health Survey; SLR=straight leg raise; SR=systematic review; TENS=Toxic Epidermal Necrosis Syndrome; TFESI=transformational epidural steroid injection; tid=three times daily; VA=Veteran's Affairs; VAS=visual analogue scale; w=week; y=year.

Please see Appendix C. Included Studies for full study references.