

Evidence Profile 5.2.3. Monoclonals vs. Placebo

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Monoclonal	Placebo	Relative (95% CI)	Absolute (95% CI)		
Pain relief (categorical) (follow up:8 week)												
1 ¹	RCT	not serious	N/A	not serious	serious	single study	8/29 (28%)	6/30 (20%)	RR 1.38 (0.55, 3.49)	76 more per 1000 (from 91 fewer to 497 more)	Very Low	CRITICAL
Pain relief (continuous) (follow up:8 weeks; assessed with: VAS; Scale: 0 to 100 [worst*])												
1 ¹	RCT	not serious	N/A	not serious	serious	single study	29	30	Average pain: Diff -2.6 (-11.8, 6.6) Worst pain: Diff -0.1 (-9.3, 9.1)		Very Low	CRITICAL
Pain relief speed												
0									not estimable	-	-	IMPORANT
Pain reduction maintenance												
0									not estimable	-	-	CRITICAL
Skeletal related events, fracture (follow up:8 weeks)												
1 ¹	RCT	not serious	N/A	not serious	very serious ^B	single study	1/29 (3.4%)	0/30 (0%)	RR 3.10 (0.13, 73.2)		Very Low	IMPORTANT
Quality of life												
0									not estimable	-	-	CRITICAL
Functional outcomes												
0									not estimable	-	-	CRITICAL
Adverse events: Osteonecrosis of the jaw												
0									not estimable			IMPORTANT

Abbreviations: **CI**: confidence interval; **Diff**: difference (between groups); **N/A**: not applicable, **NS**: not statistically significant; **RCT**: randomized controlled trial(s); **RR**: relative risk (log scale).

Explanations

A. All comparisons were statistically nonsignificant. "Any serious adverse" event occurred in 7/29 (24%) vs. 4/30 (13%) (tanezumab vs. placebo), nausea 17% vs. 7%, vomiting 7% both, arthralgia 0% vs. 3%, and constipation 10% vs. 7%.

B. Small sample size, rare events, and very wide confidence interval,

Trials

1. Sopata, M., Katz, N., Carey, W., Smith, M. D., Keller, D., Verburg, K. M., West, C. R., Wolfram, G., Brown, M. T.. Efficacy and safety of tanezumab in the treatment of pain from bone metastases. *Pain*; Sep 2015.