

Table 31: Clinical evidence profile: Comparison 2. Single IV antibiotic (with placebo) vs combination IV antibiotic for pulmonary exacerbations with *P aeruginosa*

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single IV antibiotic (with placebo)	Combination IV antibiotic	Relative (95% CI)	Absolute		
FEV₁ % predicted (absolute change) (follow-up 10 days; Better indicated by higher values) [tobramycin + placebo versus tobramycin + ceftazidime]												
1 (Mastler 2001)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	47	51	-	MD 2.2 lower (6.63 lower to 2.23 higher)	LOW	CRITICAL
FEV₁% predicted (relative change) (follow-up 2 weeks; Better indicated by higher values) [tobramycin + placebo versus IV piperacillin + tobramycin]												
1 (Maffarlane 1985)	randomised trials	serious ³	no serious inconsistency	no serious indirectness	very serious ⁴	none	4	5	-	MD 4.2 lower (26.5 lower to 18.1 higher)	VERY LOW	CRITICAL
FEV₁% predicted (relative change) (follow-up 2 weeks; Better indicated by higher values) [tobramycin + placebo versus piperacillin + tobramycin]												
1 (Maffarlane 1985)	randomised trials	serious ³	no serious inconsistency	no serious indirectness	very serious ⁴	none	4	5	-	MD 7.95 higher (8.78 lower to 24.68 higher)	VERY LOW	CRITICAL
Adverse effects - sensitivity reaction (follow-up 2 weeks; assessed with: number of participants) [tobramycin + placebo versus piperacillin all regimens]												
1 (Maffarlane 1985)	randomised trials	serious ³	no serious inconsistency	no serious indirectness	serious ⁵	none	0/8 (0%)	3/10 (30%)	RR 0.17 (0.01)	249 fewer per 1000	LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single IV antibiotic (with placebo)	Combination IV antibiotic	Relative (95% CI)	Absolute		
									to 2.96)	(from 297 fewer to 588 more)		
Adverse effects - Number of hospital admissions due to tinnitus (follow-up 2 weeks) [tobramycin + placebo versus tobramycin + ceftazidime]												
1 (Master 2001)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ⁶	none	2/47 (4.3%)	2/51 (3.9%)	RR 1.09 (0.16 to 7.4)	4 more per 1000 (from 33 fewer to 251 more)	VERY LOW	IMPORTANT
Adverse effects - serum creatinine (follow-up 2 weeks; Better indicated by lower values) [tobramycin + placebo versus tobramycin + ceftazidime]												
1 (Master 2001)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	very serious ⁶	none	21	23	-	MD 4 lower (9.38 lower to 1.38 higher)	VERY LOW	IMPORTANT
Adverse effects - serum NAG (follow-up 2 weeks; Better indicated by lower values) [tobramycin + placebo versus tobramycin + ceftazidime]												
1 (Master 2001)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	21	23	-	MD 2.1 lower (3.46 lower to 0.74 lower)	MODERATE	IMPORTANT

Abbreviations: CI: confidence interval; FEV₁: forced expiratory volume in 1 second; MD: mean difference; NAG: N-acetyl glucosamide; RR: risk ratio

1 The quality of the evidence was downgraded by 1 as each participant contributed to multiple treatment episodes.

2 The quality of the evidence was downgraded by 1 as the 95% CI crossed 1 clinical MID

3 The quality of the evidence was downgraded by 1 due to attrition bias (2 participants withdrew and did not contribute to analysis) and 1 participant received 2 treatment courses.

4 The quality of the evidence was downgraded by 2 as the 95% CI crossed 2 clinical MIDs

5 The quality of the evidence was downgraded by 1 due to very serious imprecision as 95%CI crossed 1 default MIDs

6 The quality of the evidence was downgraded by 2 as the 95% CI crossed 2 default MIDs