

Table 46: Clinical evidence profile: Comparison 5. Combination of fosfomycin + tobramycin versus placebo

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combination of fosfomycin + tobramycin	Placebo	Relative (95% CI)	Absolute		
Lung function: relative change in FEV₁% predicted (follow-up 4 weeks; range of scores: 0-100; Better indicated by higher values) [FTI 80/20 mg]												
1 (Trapnell 2012)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	no serious imprecision	none	38	32	-	MD 7.5 higher (3.6 to 11.4 higher)	MODERATE	CRITICAL
Lung function: relative change in FEV₁% predicted (follow-up 4 weeks; range of scores: 0-100; Better indicated by higher values) [FTI 160/40 mg]												
1 (Trapnell 2012)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ²	none	41	32	-	MD 6.2 higher (2.42 to 9.98 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combination of fosfomycin + tobramycin	Placebo	Relative (95% CI)	Absolute		
Suppression of the organism: sputum <i>P aeruginosa</i> density, log 10 CFU/g FTI 80/20 mg (follow-up 4 weeks; Better indicated by lower values) [FTI 80/20 mg]												
1 (Trapnell 2012)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ³	none	38	32	-	MD 1.04 lower (1.82 to 0.26 lower)	LOW	IMPORTANT
Suppression of the organism: sputum <i>P aeruginosa</i> density, log 10 CFU/g FTI 160/40 mg (follow-up 4 weeks; Better indicated by lower values) [FTI 160/40 mg]												
1 (Trapnell 2012)	randomised trials	serious ¹	no serious inconsistency	no serious indirectness	serious ³	none	41	32	-	MD 0.28 lower (1.06 lower to 0.5 higher)	LOW	IMPORTANT

Abbreviations: CFU: colony forming units; CI: confidence interval; FEV₁: forced expiratory volume in 1 second; FTI: Fosfomycin/ tobramycin inhaled; MD: mean difference; mg: milligrams; RR: risk ratio

1 The quality of the evidence was downgraded by 1 due to unclear risk of bias for allocation concealment and data reporting

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

3 The quality of the evidence was downgraded by as the 95% CI crossed 1 default MID