

Table 52: Clinical evidence profile: Comparison 3. Azithromycin versus placebo

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Azithromycin versus placebo		Relative (95% CI)	Absolute		
Time to next exacerbation (follow-up mean 6 months; assessed with: time free of exacerbation)												
2 (Saiman 2003, Saiman 2010)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	104/218 (47.7%) ¹	79/227 (34.8%)	HR 0.59 (0.44 to 0.79)	125 fewer per 1000 (from 61 fewer to 176 fewer)	HIGH	CRITICAL
								34.83%		125 fewer per 1000 (from 61 fewer to 177 fewer)		
Time to next exacerbation (follow-up 12 months)												
1 (Clement 2006)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	14/40 (35%) ¹	2/42 (4.8%)	HR 0.37 (0.217 to 0.629) ¹	30 fewer per 1000 (from 17 fewer to 37 fewer)	HIGH	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Azithromycin versus placebo		Relative (95% CI)	Absolute		
								3.6%		23 fewer per 1000 (from 13 fewer to 28 fewer)		
Mild adverse effects of antibiotic treatment - Hearing impairment (follow-up: 6 months)												
1 (Sai man 2003)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ²	none	1/87 (1.1%)	1/98 (1%)	RR 1.13 (0.07 to 17.74)	1 more per 1000 (from 9 fewer to 171 more)	LOW	CRITICAL
Mild adverse effects of antibiotic treatment – Tinnitus (follow-up: 6 months)												
1 (Sai man 2003)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ²	none	1/87 (1.1%)	1/98 (1%)	RR 1.13 (0.07 to 17.74)	1 more per 1000 (from 9 fewer to 171 more)	LOW	CRITICAL
Change in BMI z score (follow-up 12 months; Better indicated by higher values)												
1 (Clement)	randomised trials	no serious risk	no serious inconsistency	no serious indirectness	serious ³	none	40	42	-	MD 0.15 higher (0.03)	MODERATE	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Azithromycin versus placebo		Relative (95% CI)	Absolute		
2006)		of bias								lower to 0.33 higher)		
Change in weight (kg) (Follow-up: 6 months; Better indicated by higher values)												
2 (Saiman 2003, Saiman 2010)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ³	none	216	224	-	MD 0.62 higher (0.26 to 0.98 higher)	MODERATE	IMPORTANT
Quality of life: change in CFQ-R total (follow-up 6 months; range of scores: 0-100; Better indicated by higher values)												
1 (Saiman 2003)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	92	-	MD 1.6 higher (0.61 lower to 3.81 higher)	HIGH	IMPORTANT
Quality of life: change in CFQ-R physical domain score (follow-up 6 months; range of scores: 0-100; Better indicated by higher values)												
1 (Saiman 2003)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	92	-	MD 2.7 higher (0.09 to 5.31 higher)	HIGH	IMPORTANT
Quality of life: change in CFQ-R psychosocial domain score (follow-up 6 months; range of scores: 0-100; Better indicated by higher values)												
1 (Saiman)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	92	-	MD 0.4 higher (3	HIGH	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Azithromycin versus placebo		Relative (95% CI)	Absolute		
man 2003		risk of bias			imprecision					lower to 3.8 higher)		
Quality of life: change in CFQ-R body image domain score (follow-up 6 months; range of scores: 0-100; Better indicated by higher values)												
1 (Sai man 2003)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	85	92	-	MD 3.2 higher (0.24 lower to 6.64 higher)	HIGH	IMPORTANT

Abbreviations: BMI: body mass index; CFQ-R: cystic fibrosis questionnaire revised; CI: confidence interval; MD: mean difference; RR: risk ratio

1 Calculated by the NGA technical team from probability of remaining free from exacerbation.

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

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