

Summary of findings:




24. Antibiotics compared to placebo for acute otitis media – long term outcomes

Patient or population: Children aged 6 months to 15 years with acute otitis media

Setting: Primary health care.

Intervention: Antibiotics (Studies used: amoxicillin 40-90mg/kg/day three times daily, amoxicillin with clavulanate 40-90 / 5.7-6.4mg/kg/day twice daily, ampicillin 100 mg/kg/day four times daily, phenoxymethyl penicillin 50 mg/kg/day twice daily and penicillin 500-1500mg/day four times daily with dose adjusted with age. Duration was from 5-14 days.)

Comparison: Placebo

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Antibiotics	With Antibiotics	Difference		
Abnormal tympanometry assessed by: tympanometry follow up: median 3 months № of participants: 809 (3 RCTs) ^{1,c,d}	RR 0.97 (0.76 to 1.24)	24.1%	23.4% (18.3 to 29.9)	0.7% fewer (NS) (5.8 fewer to 5.8 more)	 MODERATE ^a	In children with AOM treated with antibiotics compared to placebo there is probably no difference in tympanometry findings at 3 months. NNT Not Applicable
Contralateral otitis (in unilateral cases) assessed by: otoscopy follow up: range 1 to 12 months № of participants: 906 (4 RCTs) ^e	RR 0.49 (0.25 to 0.95)	18.8%	9.2% (4.7 to 17.8)	9.6% fewer (14.1 fewer to 0.9 fewer)	 LOW ^{a,b}	In children with AOM treated with antibiotics compared to placebo there is possibly fewer contralateral AOM episodes during 12 months follow-up. NNT ~11
Late AOM recurrence assessed by: otoscope +/- parental report follow up: range 15 days to 6 months № of participants: 2200 (6 RCTs) ^f	RR 0.93 (0.78 to 1.10)	20.1%	18.7% (15.6 to 22.1)	1.4% fewer (NS) (4.4 fewer to 2 more)	 HIGH	In children with AOM treated with antibiotics compared to placebo there is no difference in late AOM recurrences during 6 months follow-up. NNT Not applicable.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; NS: Not significant; NNT: Number needed to treat; NNH: Number needed to harm

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Imprecision: Optimal information size not reached

b. Inconsistency: High heterogeneity

c. Time point chosen since persistent effusion for 3 months post AOM warrants a diagnosis of persistent OME and specific management strategies.

d. Studies taken from: Cochrane Review, Venekamp 2015 (Burke 1991, Le Saux 2005, Mygind 1981)

e. Studies taken from: Cochrane Review, Venekamp 2015 (Burke 1991, Hoberman 2011, Mygind 1981, Thalín 1985)

f. Studies taken from: Cochrane Review, Venekamp 2015 (Hoberman 2011, Kaleida 1991, Le Saux 2005, Mygind 1981, Thalín 1985, van Buchem 1981a)

References

1. Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM. Antibiotics for acute otitis media in children. The Cochrane database of systematic reviews. 2015(6):Cd000219. Epub 2015/06/24. doi: 10.1002/14651858.CD000219.pub4. PubMed PMID: 26099233.