Summary of findings:

48. Oral antibiotics compared to placebo or no treatment for children with tympanostomy tube otorrhoea

Patient or population: Children aged 6 months to 10 years with tympanostomy tube otorrhoea (TTO).

Setting: Primary health care.

Intervention: Oral antibiotics (Studies used: Amoxicillin+clavulanate 45 mg/kg/day divided into 2 doses or 30/7.5 mg/kg per day divided into 3 doses.) Duration was for 7 days.

Comparison: Placebo or no treatment.

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Oral antibiotics	**With Oral antibiotics**	**Difference**		
Resolution of ear discharge assessed with: physician assessment by otoscpy and suction. follow up: <2 weeks № of participants: 79 (1 RCT) [1,a]	**RR 2.21** (1.36 to 3.60)	32.5%	**71.8%** (44.2 to 100.0)	**39.3% more** (11.7 more to 84.5 more)	⨁⨁⨁◯ MODERATE [b,c]	In children with TTO treated with Amoxicillin+clavulanate compared with placebo there is probably more resolution of ear discharge at <2 weeks follow-up. NNT 3
Resolution of ear discharge assessed with: physician assessment by otoscopy follow up: 2 weeks № of participants: 152 (1 RCT) [1,d]	**RR 1.23** (0.90 to 1.69)	45.3%	**55.8%** (40.8 to 76.6)	10.4% more(NS) (4.5 fewer to 31.3 more)	⨁⨁◯◯ LOW [c,e]	In children with TTO treated with Amoxicillin+clavulanate compared to initial observation there is possibly no difference in ear discharge at 2 weeks follow-up. NNT Not Applicable
Adverse events (contralateral acute otitis media with perforation of the tympanic membrane, extrusion of tympanostomy tube, granulation, gastrointestinal and cutaneous) assessed with: parental report follow up: <2 weeks № of participants: 79 (1 RCT) [1,a]	**RR 1.71** (0.69 to 4.25)	15.0%	**25.7%** (10.3 to 63.7)	10.7% more(NS) (4.7 fewer to 48.8 more)	⨁⨁⨁◯ MODERATE [b,c,f]	In children with TTO treated with Amoxicillin-clavulanate compared with placebo there are probably no fewer adverse events during 2 weeks follow-up. NNH Not Applicable
Chronic ear discharge (>4 weeks) assessed with: parental report follow up: 6 months № of participants: 147 (1 RCT) [1,d]	**RR 0.41** (0.15 to 1.11)	16.4%	**6.7%** (2.5 to 18.2)	9.7% fewer (NS) (14 fewer to 1.8 more)	⨁⨁◯◯ LOW [c,e]	In children with TTO treated with Amoxicillin+clavulanate compared with placebo there is possibly no difference to report on chronic ear discharge at 6 months follow-up. NNT Not Applicable

Summary of findings:

48. Oral antibiotics compared to placebo or no treatment for children with tympanostomy tube otorrhoea

Patient or population: Children aged 6 months to 10 years with tympanostomy tube otorrhoea (TTO).

Setting: Primary health care.

Intervention: Oral antibiotics (Studies used: Amoxicillin+clavulanate 45 mg/kg/day divided into 2 doses or 30/7.5 mg/kg per day divided into 3 doses.) Duration was for 7 days.

Comparison: Placebo or no treatment.

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Oral antibiotics	**With Oral antibiotics**	**Difference**		
Tube extrusion assessed with: physician assessment and otoscopy follow up: <2 weeks № of participants: 79 (1 RCT) [1,a]	**RR 0.51** (0.05 to 5.43)	5.0%	**2.6%** (0.3 to 27.2)	2.5% fewer (NS) (4.8 fewer to 22.1 more)	⨁⨁◯◯ LOW [b,c,f,g]	In children with TTO treated with Amoxicilli+clavulanate compared with placebo there is possibly no difference to report on tube extrusion at <2 weeks 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. Studies taken from: Cochrane Review, Venekamp 2016 (Ruohola 2003)
b. Risk of Bias: Attrition bias noted but not rated down (Ruohola 2003)
c. Imprecision: Small study
d. Studies taken from: Cochrane Review, Venekamp 2016 (van Dongen 2014)
e. Risk of bias: Open label study
f. Imprecision: Low event rate
g. Imprecision: Broad estimate of effect; confidence interval includes significant both significant benefit and harm.

References

1. Venekamp RP, Javed F, van Dongen TM, Waddell A, Schilder AG. Interventions for children with ear discharge occurring at least two weeks following grommet (ventilation tube) insertion. The Cochrane database of systematic reviews. 2016;11:Cd011684. Epub 2016/11/18. doi: 10.1002/14651858.CD011684.pub2. PubMed PMID: 27854381.