Summary of findings:

45. Antibiotic(s) + corticosteroid eardrops compared to antibiotic ear-drops for children with tympanostomy tube otorrhoea

Patient or population: Children aged 6 months to 12 years with tympanostomy tube otorrhoea (TTO)

Setting: Primary health care.

Intervention: Antibiotic(s) + corticosteroid ear-drops (Studies used: Ciprofloxacin 0.3% & fluocinolone acetonide 0.025% twice daily, Ciprofloxacin (0.3%) & dexamethasone (0.1%) 3-4 drops, twice daily.) Duration was for 7 days.

Comparison: Antibiotic ear-drops (Studies used: Ofloxacin 5 drops twice daily, Ciprofloxacin 3 drops twice daily) Duration was 7-10 days.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Antibiotic(s) + corticosteroid eardrops	**With Antibiotic(s) + corticosteroid eardrops**	**Difference**		
Resolution of ear discharge assessed with: physician assessment / parental report follow up: <2 weeks № of participants: 590 (2 RCTs) [1,a]	**RR 1.76** (1.33 to 2.31)	19.9%	**35.1%** (26.5 to 46.0)	**15.1% more** (6.6 more to 26.1 more)	⨁⨁◯◯ LOW [b,c,d]	In children with TTO treated with topical antibiotic+steroid eardrops compared to topical antibiotic eardrops alone there are possibly fewer children with ear discharge at <2 weeks. NNT ~7
Adverse events assessed with: parental report follow up: <4 weeks № of participants: 1023 (3 RCTs) [1,e]	**RR 0.86** (0.55 to 1.32)	7.8%	**6.7%** (4.3 to 10.3)	1.1% fewer (NS) (3.5 fewer to 2.5 more)	⨁⨁◯◯ LOW [b,c,d]	In children with TTO treated with topical antibiotic+steroid eardrops compared to topical antibiotic eardrops alone there is possibly no difference in adverse events during 4 weeks follow-up. NNT Not Applicable
Resolution of ear discharge assessed with: physician assessment / parental report follow up: range 2 to 4 weeks № of participants: 590 (2 RCTs) [1,a]	**RR 1.09** (0.90 to 1.31)	76.0%	**82.9%** (68.4 to 99.6)	6.8% more (NS) (7.6 fewer to 23.6 more)	⨁⨁◯◯ LOW [b,d]	In children with TTO treated with topical antibiotic+steroid eardrops compared to topical antibiotic eardrops alone there is possibly no difference in children with ear discharge at 2-4 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 (Roland 2003, Roland 2004)
b. Risk of Bias: Attrition bias (Roland 2003, Roland 2004) & Performance bias - lack of participant blinding (Roland 2004)
c. Imprecision: Optimal information size not reached. Not rated down
d. Risk publication bias: 2 studies not published and not included in meta-analysis.
e. Studies taken from: Cochrane Review, Venekamp 2016 (NCT01404611, Roland 2003, Roland 2004)

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.