

Summary of findings:





50. Antibiotic eardrops (with or without a corticosteroid) compared to Oral antibiotics 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 ear-drops with or without a corticosteroid (Studies used: Ciprofloxacin 4 drops twice daily, Ofloxacin 0.25 ml twice daily, Ciprofloxacin + Hydrocortisone 4 drops twice daily, Hydrocortisone–Bacitracin–Colistin 5 drops three times daily). Duration was for 7-10 days.

Comparison: Oral antibiotics (Studies used: Amoxicillin+/-clavulanate 25-90 / 7.5 mg/kg per day divided into 2 to 3 doses.) Duration was for 7-10 days. In case of penicillin allergy, erythromycin, 40 mg/kg/day divided into 3 doses daily for 7 days was chosen.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)		Difference	Certainty	What happens
Resolution of ear discharge follow up: 1 weeks № of participants: 42 (1 RCT) ^{1,a}	RR 2.58 (1.27 to 5.22)	30.0%	77.4% (38.1 to 100.0)	47.4% more (8.1 more to 126.6 more)	 MODERATE ^{b,c}	In children with TTO treated with Ciprofloxacin compared to Amoxicillin there is probably more resolution of ear discharge at one week follow-up. NNT ~3
Resolution of ear discharge - Antibiotic-corticosteroid eardrops versus oral antibiotics follow up: range 2 to 4 weeks № of participants: 232 (2 RCTs) ^{1,d}	RR 1.59 (1.35 to 1.88)	57.3%	91.1% (77.3 to 100.0)	33.8% more (20 more to 50.4 more)	 LOW ^{c,e}	In children with TTO treated with antibiotic+steroid eardrops compared to oral antibiotics there is possibly more resolution of ear discharge at two to four weeks follow-up. NNT ~3
Resolution of ear discharge - Antibiotic-corticosteroid eardrops versus oral antibiotics (Sensitivity analysis) follow up: median 2 weeks № of participants: 153 (1 RCT) ^{1,f}	RR 1.70 (1.38 to 2.08)	55.8%	94.9% (77.1 to 100.0)	39.1% more (21.2 more to 60.3 more)	 MODERATE ^c	In children with TTO treated with antibiotic+steroid eardrops compared to oral antibiotics there is possibly more resolution of ear discharge at two weeks follow-up. NNT ~3
Resolution of ear discharge - Antibiotic-only eardrops versus oral antibiotics follow up: range 2 to 4 weeks № of participants: 233 (1 RCT) ^{1,g}	RR 1.00 (0.91 to 1.09)	89.4%	89.4% (81.3 to 97.4)	0.0% fewer (NS) (8 fewer to 8 more)	 LOW ^{c,e}	In children with TTO treated with Ofloxacin eardrops compared to Amoxicillin+clavulanate there is possibly no difference in ear discharge at 2-4 weeks follow-up. NNT Not applicable

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Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)		Difference	Certainty	What happens
Adverse events (ear pain, gastrointestinal) follow up: range 2 to 3 weeks № of participants: 705 (3 RCTs) ^{1,h}	RR 0.37 (0.12 to 1.09)	31.7%	11.7% (3.8 to 34.5)	20.0% fewer (NS) (27.9 fewer to 2.9 more)	 LOW ^{c,e,i}	In children with TTO treated with antibiotic+/-steroid eardrops compared to oral antibiotics there is possibly no difference to report on adverse effects at 2-3 weeks follow-up. NNT Not Applicable
Proportion of patients with chronic ear discharge (>4 weeks) follow up: 6 months № of participants: 148 (1 RCT) ^{1,f}	RR 0.20 (0.02 to 1.67)	6.8%	1.4% (0.1 to 11.3)	5.4% fewer (NS) (6.6 fewer to 4.5 more)	 LOW ^{c,e}	In children with TTO treated with hydrocortisone–bacitracin–colistin eardrops compared to amoxicillin+clavulanate there is possibly no difference to report on chronic ear discharge at 6 months follow-up. NNT Not Applicable
Proportion of patients with tube blockage follow up: range 1 to 3 weeks № of participants: 121 (2 RCTs) ⁱ	RR 1.20 (0.33 to 4.45)	5.0%	6.0% (1.7 to 22.3)	1.0% more (NS) (3.3 fewer to 17.3 more)	 VERY LOW ^{c,e}	In children with TTO treated with antibiotic+/-steroid ear drops compared to oral antibiotics there is possibly no difference to report on tube blockage. NNT Not Applicable
QOL scores - measured with otitis media-6 questionnaire assessed with: parental report follow up: 2 weeks № of participants: 153 (1 RCT) ^{1,f}	The changes in Otitis Media-6 total score (range 6 to 42) at two weeks were small, but favoured the antibiotic-corticosteroid eardrops group (difference in median change between treatment groups: -2, P < 0.01).				 LOW ^{c,e}	In children with TTO treated with hydrocortisone–bacitracin–colistin eardrops compared to amoxicillin+clavulanate there are possibly better QOL scores at 2 weeks follow-up.

*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 (Heslop 2010)

- b. Risk of bias: Lack of participant blinding however not rated down (outcome assessors blinded and adequate allocation concealment)
- c. Imprecision: Small study / optimal information size not reached
- d. Studies taken from: Cochrane Review, Venekamp 2016 (Dohar 2006, van Dongen 2014)
- e. Risk of bias: Open label trial, stopped early due to recommendation by committee given results of interim analysis - not rated down for this (van Dongen); attrition bias (Goldblatt); performance bias (Goldblatt and Dohar)
- f. Studies taken from: Cochrane Review, Venekamp 2016 (van Dongen 2014)
- g. Studies taken from: Cochrane Review, Venekamp 2016 (Goldblatt 1998)
- h. Studies taken from: Cochrane Review, Venekamp 2016 (Dohar 2006, Goldblatt 1998, van Dongen 2014)
- i. Inconsistency: High heterogeneity explained by excluding van Dongen. Not rated down.
- j. Studies taken from: Cochrane Review, Venekamp 2016 (Dohar 2006, Heslop 2010)

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.