Summary of findings:

17. Oral steroids compared to placebo for otitis media with effusion

Patient or population: Children aged 6 months to 14 years with otitis media with effusion

Setting: Primary health care.

Intervention: Oral steroids [Prednisolone (0.5-1.5 mg/kg daily (max 30 mg) in divided dose tapering over 7 or 14 days), Dexamethasone (0.15 mg/kg daily in divided dose tapering over 14 days) and Betamethasone (6mg as single dose)]

Comparison: Placebo

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Oral steroids	**With Oral steroids**	**Difference**		
Hearing loss (Proportion of children who fail to improve by >10dB in either ear) assessed with: pure tone audiometry follow up: 6 weeks № of participants: 49 (1 RCT) [1,a]	**RR 1.09** (0.80 to 1.49)	73.9%	**80.6%** (59.1 to 100.0)	6.7% more(NS) (14.8 fewer to 36.2 more)	⊕⊕○○ LOW [b,c,d]	In children with OME treated with oral steroids compared to placebo there is possibly no difference in hearing improvement of > 10 dB at 6 weeks. NNT Not Applicable.
OME resolution (two weeks) assessed with: pneumo-otoscopy & tympanometry № of participants: 108 (3 RCTs) [1,e]	**RR 3.80** (0.93 to 15.52)	5.8%	**21.9%** (5.4 to 89.5)	16.2% more(NS) (0.4 fewer to 83.8 more)	⊕⊕⊕○ MODERATE [c,f]	In children with OME treated with oral steroids compared to placebo there is probably no increase in OME resolution at 2 weeks. NNT Not Applicable
OME resolution assessed with: pneumo-otoscopy & tympanometry follow up: range 4 to 6 weeks № of participants: 106 (3 RCTs) [1,e]	**RR 1.54** (0.76 to 3.14)	17.6%	**27.2%** (13.4 to 55.4)	9.5% more(NS) (4.2 fewer to 37.8 more)	⊕⊕○○ LOW [c,f,g]	In children with OME treated with oral steroids compared to placebo there possibly no increase in OME resolution at 4-6 weeks. 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, Simpson 2011 (Macknin 1985)
b. Risk of bias: Study terminated early due to concern that steroid was impairing resolution. Likely to result in lack of power rather than bias.
c. Imprecision: Small numbers / optimal information size not reached
d. Imprecision: single study
e. Studies taken from: Cochrane Review, Simpson 2011 (Giebink 1990, Macknin 1985, Niederman 1984)
f. Inconsistency: Different treatments and regimens between studies, however low heterogeneity of pooled data.

g. Risk of Bias: Attrition bias (Niederman 1984), some imbalance in baseline characteristics (Niederman 1984), allocation concealment / selection bias not described across all studies.

References

1.	Simpson SA, Lewis R, van der Voort J, Butler CC. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. The Cochrane database of systematic reviews. 2011(5):Cd001935. Epub 2011/05/13. doi: 10.1002/14651858.CD001935.pub3. PubMed PMID: 21563132.