Summary of findings:

18 Oral steroids compared to placebo for otitis media with effusion (antibiotics in both arms of studies)

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

Setting: Primary health care and Hospital

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)] and Antibiotics [Amoxicillin (0.5 mg/kg twice daily on days 1 through 10 (total daily dose 1 mg/kg, maximum 30 mg/d), then days 11 through 14 given once daily (total daily dose 0.5 mg/kg, maximum 15 mg/d); then 40 mg/kg/d in 3 divided doses from days 15 through 28), Trimethoprim/sulfamethoxazole (5mg/kg/dose twice daily 30 days or 50 mg/kg/day twice daily for 7 days) and Cefixime for 10 days used across studies).

Comparison: Placebo and Antibiotics (Amoxicillin, Trimethoprim/sulfamethoxazole and Cefixime used across studies)

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Oral steroids	**With Oral steroids**	**Difference**		
OME resolution (short term follow-up) assessed with: otoscopy, pneumatic otoscope, tympanometry +/- audiometry. follow up: range 7 to 28 days № of participants: 409 (5 RCTs) [1,a]	**RR 1.99** (1.14 to 3.49)	23.1%	**46.0%** (26.4 to 80.7)	**22.9% more** (3.2 more to 57.6 more)	⨁⨁◯◯ LOW [b,c,d]	In children with OME treated antibiotics, adjunct oral steroids compared to placebo there is possibly improve resolution of OME at 7 to 28 days. NNT ~5
Adverse effects - mild to moderate Assessed with: parental report follow up: range 2 weeks to 6 months № of participants: 255 (2 RCTs) [1,e,f]	**RR 1.34** (0.84 to 2.14)	18.1%	**24.3%** (15.2 to 38.8)	6.2% more (NS) (2.9 fewer to 20.6 more)	⨁⨁⨁◯ MODERATE [g,b,h]	In children with OME treated antibiotics, adjunct oral steroids compared to placebo there is there is probably no difference in adverse events. 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 (Berman 1990, Hemlin 1997, Lambert 1986, Mandel 2002, Schwartz 1980)
b. Imprecision: Small numbers / optimal information size not reached
c. Risk of bias: attrition bias (Berman 1990). Poor reporting with unclear risk of bias on many aspects of several studies. Not rated down.
d. Inconsistency: High heterogeneity likely due to different medications and regimens used in pooled studies.
e. Adverse effects included: dermatological, gastrointestinal, hyperactivity and irritability. No serious adverse effects reported. In Mandel 2002 treatments were administered in two phases (four-arm study analysed as two-arm) and adverse effects reported separately for both phases; data from end of first phase (completion of two-week steroid treatment) used in meta-analysis. No patients withdrew medications due to steroids. In Hemlin 1997 follow-up was until 6 months however treatment failures at visit 2 were not followed up beyond that time frame.
f. Studies taken from: Cochrane Review, Simpson 2011 (Hemlin 1997, Mandel 2002)
g. Risk of bias: Study terminated early due to concern that steroid was impairing resolution. Likely to result in lack of power rather than bias.
h. Inconsistency: Different treatments and regimens between studies, however low heterogeneity of pooled data.

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.