Summary of findings:

16. Topical / intranasal steroids compared to placebo for otitis media with effusion

Patient or population: Children aged 2 to 12 years with otitis media with effusion.

Setting: Primary health care.

Intervention: Topical / Intranasal steroids (Studies used: Aerosolised dexamethasone1 spray each nostril, 3 times a day and mometasone furoate 50 - 200mcg once daily.) Duration was for 3 to 16 weeks.

Comparison: Placebo.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Topical / Intranasal steroids	**With Topical / Intranasal steroids**	**Difference**		
Hearing Loss assessed with: Fail audiometry sweep at 25dB HL; fail on more than two out of five frequencies in both ears follow up: 9 months № of participants: 141 (1 RCT) [1,a]	**RR 1.17** (0.87 to 1.58)	50.7%	**59.4%** (44.1 to 80.2)	8.6% more (NS) (6.6 fewer to 29.4 more)	⨁⨁◯◯ LOW [b,c]	In children with OME treated with intranasal steroids compared to placebo there is possibly no improvement in hearing outcomes at 9 months. NNT Not applicable
Resolution OME - short term assessed with: pneumo-otoscopy +/- tympanometry follow up: range 3 weeks to 4 weeks № of participants: 238 (2 RCTs) [1,d]	**RR 0.85** (0.63 to 1.15)	46.3%	**39.3%** (29.2 to 53.2)	6.9% fewer (NS) (17.1 fewer to 6.9 more)	⨁⨁⨁◯ MODERATE [c,e]	In children with OME treated with intranasal steroids compared to placebo there is probably no difference in resolution of OME in the short term. NNT Not applicable
Resolution OME - medium term assessed with: pneumo-otoscopy +/- tympanometry follow up: range 3 to 6 months № of participants: 234 (2 RCTs) [1,2,f]	**RR 1.42** (0.85 to 2.37)	51.7%	**73.4%** (43.9 to 100.0)	21.7% more (NS) (7.8 fewer to 70.8 more)	⨁⨁◯◯ LOW [c,g,h]	In children with OME treated with intranasal steroids compared to placebo there is insufficient evidence to report on resolution of OME at 3-6 months. NNT Not applicable
Resolution OME - long term assessed with: pneumo-otoscopy +/- tympanometry follow up: median 9 months № of participants: 144 (1 RCT) [1,a]	**RR 0.85** (0.65 to 1.11)	65.3%	**55.5%** (42.4 to 72.5)	9.8% fewer (NS) (22.8 fewer to 7.2 more)	⨁⨁◯◯ LOW [b,h]	In children with OME treated with intranasal steroids compared to placebo there is insufficient evidence to report on resolution of OME at 9 months. NNT Not applicable

Summary of findings:

16. Topical / intranasal steroids compared to placebo for otitis media with effusion

Patient or population: Children aged 2 to 12 years with otitis media with effusion.

Setting: Primary health care.

Intervention: Topical / Intranasal steroids (Studies used: Aerosolised dexamethasone1 spray each nostril, 3 times a day and mometasone furoate 50 - 200mcg once daily.) Duration was for 3 to 16 weeks.

Comparison: Placebo.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Topical / Intranasal steroids	**With Topical / Intranasal steroids**	**Difference**		
Adverse effects (No major adverse effects reported. Minor adverse effects during treatment includes: cough, dry throat, epistaxis, nasal stinging) assessed with: parental report follow up: range 2 weeks to 6 months № of participants: 234 (2 RCTs) [1,2,f]	**RR 1.21** (0.78 to 1.89)	22.0%	**26.7%** (17.2 to 41.6)	4.6% more (NS) (4.8 fewer to 19.6 more)	⨁⨁⨁◯ MODERATE [c,h]	In children with OME treated with intranasal steroids compared to placebo there is probably no difference in adverse effects. NNT Not applicable
Quality of life score assessed with: Glasgow Children Benefit Inventory follow up: mean 24 weeks № of participants: 62 (1 RCT) [2 i]	Glasgow Children Benefit Inventory showed statistically significant improvement in QOL with score of 37.11 +/- 25.5 (topical steroids) vs 11.02 +/-19.8 (placebo) (p value 0.0001).				⨁⨁◯◯ LOW [c,i]	In children with OME treated with intranasal steroids compared to placebo there is possibly some improvement in QOL scores.

***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; **MD:** Mean difference

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 (Williamson 2009)
b. Risk of Bias: Attrition bias
c. Imprecision: Broad estimate of effect. Confidence interval covers significant benefit and harm. Single, small study.
d. Studies taken from: Cochrane Review, Simpson 2011 (Shapiro 1982, Williamson 2009)
e. Inconsistency: Different measures for OME resolution between studies, however low heterogeneity between studies on statistical analysis.

f. Studies taken from: Cochrane Review, Simpson 2011 (Williamson 2009) and Bhargava 2014
g. Inconsistency: High heterogeneity - rate of OME clearance very different between studies which may be due to inclusion criteria. Bhargava recruited via tertiary ENT service with adenoid hypertrophy, whilst Williamson recruited via primary care with 3 months of OME.
h. Imprecision: Optimal information size not met.
i. Indirectness: Not specifically evaluated for children with hearing loss due to OME

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.
2. Bhargava R, Chakravarti A. A double-blind randomized placebo-controlled trial of topical intranasal mometasone furoate nasal spray in children of adenoidal hypertrophy with otitis media with effusion. American journal of otolaryngology. 2014;35(6):766-70. Epub 2014/08/26. doi: 10.1016/j.amjoto.2014.06.006. PubMed PMID: 25151658.