Summary of findings:

37 Oral Trimethoprim/Sulfamethoxazole compared to placebo for adjunct treatment (with topical quinolones) for chronic suppurative otitis media.

Patient or population: Children aged 1 to 12 years with chronic suppurative otitis media (TMP).

Setting: Primary health care.

Intervention: Oral Trimethoprim/Sulfamethoxazole (8 mg/kg/day - trimethoprim component - in two divided doses) adjunct treatment (with topical quinolones) for 6 to 12 weeks.

Comparison: Placebo adjunct treatment (with topical quinolones)

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Oral Trimethoprim/ Sulfamethoxazole	**With Oral Trimethoprim/ Sulfamethoxazole**	**Difference**		
Persistent otorrhoea assessed with: otoscopy follow up: mean 6 weeks № of participants: 98 (1 RCT) [1,a]	**RR 0.52** (0.31 to 0.89)	52.9%	**27.5%** (16.4 to 47.1)	**25.4% fewer** (36.5 fewer to 5.8 fewer)	⨁⨁⨁◯ MODERATE [b]	In children with CSOM treated with TMP-SMX as an adjunct to topical therapy compared to topical therapy alone there are probably fewer children with persistent otorrhoea at 6 weeks follow-up. NNT ~4
Persistent otorrhoea assessed with: otoscopy follow up: mean 12 weeks № of participants: 96 (1 RCT) [1,a]	**RR 0.68** (0.41 to 1.14)	46.9%	**31.9%** (19.2 to 53.5)	15.0% fewer (NS) (27.7 fewer to 6.6 more)	⨁⨁⨁◯ MODERATE [b]	In children with CSOM treated with TMP-SMX as an adjunct to topical therapy compared to topical therapy alone there is probably no difference in persistent otorrohoea at 12 weeks follow-up. NNT Not Applicable
Persistent otorrhoea assessed with: otoscopy follow up: mean 1 years № of participants: 90 (1 RCT) [1,a,c]	**RR 1.28** (0.59 to 2.78)	19.6%	**25.0%** (11.5 to 54.4)	5.5% more (NS) (8 fewer to 34.8 more)	⨁⨁◯◯ LOW [b,d]	In children with CSOM treated with TMP-SMX as an adjunct to topical therapy compared to topical therapy alone there is possibly no difference in persistent otorrhoea at 1 year follow-up. NNT Not Applicable
Adverse events (diarrhoea or vomiting) assessed with: parental report follow up: mean 6 weeks № of participants: 98 (1 RCT) [1,a]	**RR 4.34** (0.50 to 37.46)	2.0%	**8.5%** (1.0 to 73.5)	6.5% more (NS) (1 fewer to 71.5 more)	⨁⨁⨁◯ MODERATE [b]	Children with CSOM treated with TMP-SMX as adjunct to topical therapy versus topical therapy alone probably results in no difference in adverse effects. NNH 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

Summary of findings:

37 Oral Trimethoprim/Sulfamethoxazole compared to placebo for adjunct treatment (with topical quinolones) for chronic suppurative otitis media.

Patient or population: Children aged 1 to 12 years with chronic suppurative otitis media (TMP).

Setting: Primary health care.

Intervention: Oral Trimethoprim/Sulfamethoxazole (8 mg/kg/day - trimethoprim component - in two divided doses) adjunct treatment (with topical quinolones) for 6 to 12 weeks.

Comparison: Placebo adjunct treatment (with topical quinolones)

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Oral Trimethoprim/ Sulfamethoxazole	**With Oral Trimethoprim/ Sulfamethoxazole**	**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. Study taken from: van der Veen 2007
b. Imprecision: Small study
c. After 12 weeks study medication discontinued and patients referred back to care provider. Treatment recommendation in case otorrhea was: trimethoprim/ sulfamethoxazole (18 mg/kg, 2 times per day, for 6–12 weeks) for the placebo group and azithromycin (5 mg/ kg, once per day, for 6–12 weeks) for the trimethoprim/ sulfamethoxazole group, however this was up to discretion of doctor and other treatment could be offered.
d. Risk of Bias: Performance bias (lack blinding)

References

1. van der Veen, E. L. Rovers,M. M. Albers,F. W. Sanders,E. A. Schilder,A. G.. Effectiveness of trimethoprim/sulfamethoxazole for children with chronic active otitis media: a randomized, placebo-controlled trial. Pediatrics; 2007.