Summary of findings:

29 Prophylactic antibiotics compared to placebo / no treatment for prevention of recurrent acute otitis media

Patient or population: Prevention of recurrent acute otitis media in children aged 0 to 14 years.

Setting: Primary health care.

Intervention: Prophylactic antibiotics (Studies used Amoxycillin 20-50mg/kg daily, Ampicillin 125-250mg/day (dose age dependant), Trimethoprim/sulfamethoxazole 4-8/12-40 mg/kg/day twice daily, Sulfisoxazole 75 mg/kg/day or 500-1000mg (dose age dependant) twice daily and Phenoxymethyl penicillin V 25 mg/kg/day). Duration was 6.5 weeks to 2 years.

Comparison: Placebo / no treatment

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Prophylactic antibiotics	**With Prophylactic antibiotics**	**Difference**		
Prevention - any AOM or CSOM during treatment assessed by: clinical assessment, pneumatic otoscope / otoscope +/- tympanostomy. follow up: range 10 weeks to 24 months № of participants: 1461 (14 RCTs) [1,a]	**RR 0.65** (0.53 to 0.79)	55.7%	**36.2%** (29.5 to 44.0)	**19.5% fewer** (26.2 fewer to 11.7 fewer)	⨁⨁⨁◯ MODERATE [b]	In children with rAOM treated with prophylactic antibiotics compared to placebo/no treatment there are probably fewer AOM episodes during treatment at 2-24 months. NNT ~5
Prevention - episodes of AOM or CSOM during treatment assessed by: clinical assessment, pneumatic otoscope / otoscope +/- tympanostomy. follow up: range 10 weeks to 24 months № of participants: 1327 (13 RCTs) [1,c]	**Incidence Rate Ratio 0.51** (0.39 to 0.66)				⨁⨁⨁◯ MODERATE [b]	In children with rAOM treated with prophylactic antibiotics compared to placebo/no treatment there are probably fewer episodes of AOM during Rx. Prevents ~1.5 episodes per year of treatment, per child.
Adverse effects (any clinical side effects during intervention) assessed by: parental report follow up: range 10 weeks to 24 months № of participants: 817 (12 RCTs) [1,d]	**RR 1.99** (0.25 to 15.89)	0.8%	**1.7%** (0.2 to 13.2)	0.8% more (NS) (0.6 fewer to 12.4 more)	⨁◯◯◯ VERY LOW [b,e]	In children with rAOM treated with prophylactic antibiotics compared to placebo/no treatment there is possibly no difference to report on adverse effects during 24 months follow-up. NNH Not Applicable

Summary of findings:

29 Prophylactic antibiotics compared to placebo / no treatment for prevention of recurrent acute otitis media

Patient or population: Prevention of recurrent acute otitis media in children aged 0 to 14 years.

Setting: Primary health care.

Intervention: Prophylactic antibiotics (Studies used Amoxycillin 20-50mg/kg daily, Ampicillin 125-250mg/day (dose age dependant), Trimethoprim/sulfamethoxazole 4-8/12-40 mg/kg/day twice daily, Sulfisoxazole 75 mg/kg/day or 500-1000mg (dose age dependant) twice daily and Phenoxymethyl penicillin V 25 mg/kg/day). Duration was 6.5 weeks to 2 years.

Comparison: Placebo / no treatment

Outcome № of participants (studies)	Relative effect (95% CI)	**Anticipated absolute effects (95% CI)**			Quality	What happens
		Without Prophylactic antibiotics	**With Prophylactic antibiotics**	**Difference**		
Antibiotic resistance during intervention assessed by: nasopharyngeal swabs follow up: range 12 to 24 months № of participants: 181 (2 RCTs) [1,f]	**RR 1.37** (0.83 to 2.26)	22.5%	**30.8%** (18.7 to 50.8)	8.3% more(NS) (3.8 fewer to 28.3 more)	⨁⨁◯◯ LOW [g,h]	In children with rAOM treated with prophylactic antibiotics compared to placebo there is possibly no difference to report on antibiotic resistance. NNT Not applicable. 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

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: (1) Cochrane Review, Leach 2006 updated 2011 (Casselbrant 1992 Gaskins 1982, Gonzalez 1986, Liston 1983, Leach 2008, Mandel 1996, Maynard 1972, Perrin 1974, Persico 1985, Principi 1989, Roark 1997, Sih 1993, Teele 2000, Varsano 1985)
b. Inconsistency: High heterogeneity
c. Studies taken from: (1) Cochrane Review, Leach 2006 updated 2011 (Casselbrant 1992, Gray 1981, Gaskins 1982, Gonzalez 1986, Liston 1983, Leach 2008, Mandel 1996, Maynard 1972, Principi 1989, Roark 1997, Sih 1993, Schuller 1983a, Varsano 1985)
d. Studies taken from: (1) Cochrane Review, Leach 2006 updated 2011 (Casslebrant 1992, Gaskins 1982a, Gonzales 1986, Gray 1981, Leech 2008, Perrin 1974, Principi 1989a, Sih 1993a, Schuller 1983a, Teele 2000a, Versano 1985)
e. Imprecision: Low event rate. Optimal information size not reached. Confidence interval covers benefit and harm.
f. Studies taken from: Cochrane Review, Leach 2006 (Casslebrant 1992, Mandel 1996)
g. Indirectness: Nasopharyngeal carriage of only a small number of specific bacteria reported. Surrogate marker for clinically important resistant disease.
h. Imprecision: Optimal information size not reached

References

1. Leach AJ, Morris PS. Antibiotics for the prevention of acute and chronic suppurative otitis media in children. The Cochrane database of systematic reviews. 2006(4):Cd004401. Epub 2006/10/21. doi: 10.1002/14651858.CD004401.pub2. PubMed PMID: 17054203.