

Summary of findings:





28. Immediate antibiotics compared to watchful waiting for acute otitis media

Patient or population: Children aged 6 months to 16 years with acute otitis media

Setting: Primary health care

Intervention: Immediate antibiotics (Studies used: Amoxycillin 90mg/kg/day twice daily for 7 to 10 days and Phenoxyethylpenicillin 50mg/kg/day twice daily for 5 days)

Comparison: Watchful waiting

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Immediate antibiotics	With Immediate antibiotics	Difference		
Pain assessed: parental report follow up: range 3 to 7 days № of participants: 959 (4 RCTs) ^{1,a}	RR 0.75 (0.50 to 1.12)	35.6%	26.7% (17.8 to 39.8)	8.9% fewer (NS) (17.8 fewer to 4.3 more)	 MODERATE ^b	In children with AOM treated with immediate antibiotics compared to watchful waiting there is probably no less pain at 3-7 days. NNT Not Applicable.
Pain assessed: parental report follow up: range 11 to 14 days № of participants: 247 (1 RCT) ^{1,c}	RR 0.91 (0.75 to 1.10)	66.9%	60.9% (50.2 to 73.6)	6.0% fewer(NS) (16.7 fewer to 6.7 more)	 LOW ^{b,d,e}	In children with AOM treated with immediate antibiotics compared to watchful waiting there is possibly no less pain at 11-14 days. NNT Not Applicable.
Adverse effects (vomiting, diarrhoea or rash) assessed: parental report follow up: range 7 to 40 days № of participants: 550 (2 RCTs) ^{1,f}	RR 1.71 (1.24 to 2.36)	16.7%	28.5% (20.7 to 39.3)	11.8% more (4 more to 22.7 more)	 MODERATE ^e	In children with AOM treated with immediate antibiotics compared to watchful waiting there is probably more adverse events at 7-40 days follow-up. NNH ~ 9
Abnormal tympanometry assessed: tympanometry follow up: median 4 weeks № of participants: 207 (1 RCT) ^{1,g}	RR 1.03 (0.78 to 1.35)	49.5%	51.0% (38.6 to 66.8)	1.5% more(NS) (10.9 fewer to 17.3 more)	 LOW ^{d,e}	In children with AOM treated with immediate antibiotics compared to watchful waiting there is probably no difference to report a difference in tympanometry findings. NNT Not Applicable.

Summary of findings:




28. Immediate antibiotics compared to watchful waiting for acute otitis media

Patient or population: Children aged 6 months to 16 years with acute otitis media

Setting: Primary health care

Intervention: Immediate antibiotics (Studies used: Amoxicillin 90mg/kg/day twice daily for 7 to 10 days and Phenoxyethylpenicillin 50mg/kg/day twice daily for 5 days)

Comparison: Watchful waiting

Outcome No of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Immediate antibiotics	With Immediate antibiotics	Difference		
Tympanic membrane perforation assessed: otoscopy follow up: median 3 months No of participants: 179 (1 RCT) ^{1,h}	not estimable	0.0%	0.0% (0.0 to 0.0)	0.0% fewer (0 fewer to 0 fewer)	 MODERATE ^{e,i}	In children with AOM treated with immediate antibiotics compared to watchful waiting there is probably no difference to report on TM perforation as sequelae of AOM.
AOM recurrences assessed: acute ear symptoms / abnormal tympanic membrane / AOM severity score higher than that at enrolment follow up: range 13 to 30 days No of participants: 209 (1 RCT) ^{1,g}	RR 1.41 (0.74 to 2.69)	13.0%	18.3% (9.6 to 35.0)	5.3% more(NS) (3.4 fewer to 22 more)	 LOW ^{d,e,j}	In children with AOM treated with immediate antibiotics compared to watchful waiting there is probably no difference to report on AOM recurrences. NNT Not Applicable.
Outpatient antibiotic prescriptions No of participants: 313932 (1 observational study) ^{2,j}	Large Israeli observational study. Guidelines introduced in 2004 which recommended watchful waiting. Pre-guideline prescription rates for first episode AOM in children >24 months was 56%. From 2004 to 2007, rate decreased to 47%.				 VERY LOW ^k	In children with AOM treated with immediate antibiotics compared to watchful waiting there is possibly a reduction of antibiotic prescriptions.

*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, Venekamp 2015 (Little 2001, McCormick 2005, Spiro 2006, Neumark 2007)
- b. Imprecision: Confidence interval for estimate of effect covers both benefit and harm.
- c. Studies taken from: Cochrane Review, Venekamp 2015 (Spiro 2006)
- d. Risk of bias: Attrition bias
- e. Imprecision: Optimal information size not reached
- f. Studies taken from: Cochrane Review, Venekamp 2015 (Little 2001, Spiro 2006)
- g. Studies taken from: Cochrane Review, Venekamp 2015 (McCormick 2005)
- h. Studies taken from: Cochrane Review, Venekamp 2015 (Neumark 2007)
- i. Imprecision: Low event rate
- j. Grossman 2010
- k. Script rates are a surrogate for overall antibiotic consumption, itself only important insofar as it promotes resistance, which was not measured here

References

1. Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM. Antibiotics for acute otitis media in children. The Cochrane database of systematic reviews. 2015(6):Cd000219. Epub 2015/06/24. doi: 10.1002/14651858.CD000219.pub4. PubMed PMID: 26099233.
2. Grossman Z, Silverman BG, Porter B, Miron D. Implementing the delayed antibiotic therapy approach significantly reduced antibiotics consumption in Israeli children with first documented Acute otitis media. The Pediatric infectious disease journal. 2010;29(7):595-9. Epub 2010/07/01. PubMed PMID: 20589979.