

Summary of findings:




20. Oral analgesia compared to placebo for pain relief in acute otitis media

Patient or population: Children aged 1 to 6.75 years with acute otitis media and pain

Setting: Primary health care

Intervention: Oral analgesia (Paracetamol 10mg/kg/dose three times daily and NSAID - ibuprofen 10mg/kg/dose three times daily)

Comparison: Placebo

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Placebo	With paracetamol / NSAID	Difference		
Pain - Paracetamol compared to placebo assessed with: parental report follow up: median 48 hours № of participants: 148 (1 RCT) ^{1, a}	RR 0.38 (0.17 to 0.85)	25.3%	9.6% (4.3 to 21.5)	15.7% fewer (21 fewer to 3.8 fewer)	 LOW ^{b,c}	In children with AOM treated with Paracetamol compared to placebo there is possibly less pain reported at 48 hours. NNT ~6
Pain - NSAID compared to placebo assessed with: parental report follow up: median 48 hours № of participants: 146 (1 RCT) ^{1, a}	RR 0.28 (0.11 to 0.70)	25.3%	7.1% (2.8 to 17.7)	18.2% fewer (22.5 fewer to 7.6 fewer)	 LOW ^{b,c}	In children with AOM treated with NSAIDs compared to placebo there is possibly less pain reported at 48 hours. NNT ~6
Adverse events (nausea, vomiting, abdominal pain & cutaneous rash) - Paracetamol compared to placebo assessed with: parental report follow up: median 48 hours № of participants: 148 (1 RCT) ^{1, a}	RR 1.03 (0.21 to 4.93)	4.0%	4.1% (0.8 to 19.7)	0.1% more(NS) (3.2 fewer to 15.7 more)	 VERY LOW ^{b,c,d}	In children with AOM treated with Paracetamol compared to placebo there is insufficient evidence to report on adverse events. NNH Not Applicable

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		Placebo	With paracetamol / NSAID	Difference		
Adverse events (nausea, vomiting, abdominal pain & cutaneous rash) - NSAID compared to placebo assessed with: parental report follow up: median 48 hours No of participants: 146 (1 RCT) ^{1,a}	RR 1.76 (0.44 to 7.10)	4.0%	7.0% (1.8 to 28.4)	3.0% more(NS) (2.2 fewer to 24.4 more)	 VERY LOW ^{b,d}	In children with AOM treated with NSAIDs compared to placebo there is insufficient evidence to report on adverse events. 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

- Studies taken from: Cochrane Review, Sjoukes 2016 (Bertin 1996)
- Indirectness: Antibiotics given to patient concurrently with analgesia during study
- Imprecision: Optimal information size not met.
- Imprecision: Broad estimate of effect.

References

- Sjoukes A, Venekamp RP, van de Pol AC, Hay AD, Little P, Schilder AG, et al. Paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs, alone or combined, for pain relief in acute otitis media in children. The Cochrane database of systematic reviews. 2016;12:CD011534. Epub 2016/12/16. doi: 10.1002/14651858.CD011534.pub2. PubMed PMID: 27977844.