

Summary of findings:





19 Antihistamines and/or decongestants compared to placebo for otitis media with effusion

Patient or population: Children aged 5 months to 15 years with otitis media with effusion

Setting: Primary health care

Intervention: Antihistamines and/or decongestants (Studies used: chlorpheniramine & pseudoephedrine, ebastine, cinnarizine, oxymetazoline, phenylpropranolamine, phenylpropranolamine & brompheniramine, triprolidine & pseudoephedrine, phenylephrine, diphenhydramine & pseudoephedrine)

Comparison: Placebo

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Antihistamines and/or decongestants	With Antihistamines and/or decongestants	Difference		
Hearing assessed with: <20dB hearing improvement or no improvement follow up: median 1 months № of participants: 358 (3 RCTs) ^{1,a}	RR 1.08 (0.93 to 1.27)	60.2%	65.0% (56.0 to 76.5)	4.8% more (NS) (4.2 fewer to 16.3 more)	 LOW ^{b,c}	In children with OME treated with antihistamines and/or decongestants compared with placebo there is possibly no hearing improvement during 1 month follow-up. NNT Not Applicable
Hearing assessed with: <20dB hearing improvement or no improvement follow up: median 1 years № of participants: 48 (1 RCT) ^{1,d}	RR 1.50 (0.63 to 3.56)	25.0%	37.5% (15.8 to 89.0)	12.5% more(NS) (9.3 fewer to 64 more)	 LOW ^c	In children with OME treated with antihistamines and/or decongestants compared with placebo there is possibly no hearing improvement at 1 year. NNT Not Applicable
Persistent OME assessed with: tympanometry and otoscopy follow up: median 1 months № of participants: 1177 (6 RCTs) ^{1,e}	RR 0.99 (0.92 to 1.05)	74.9%	74.1% (68.9 to 78.6)	0.7% fewer (NS) (6 fewer to 3.7 more)	 MODERATE ^{b,f}	In children with OME treated with antihistamines and/or decongestants compared with placebo there is probably no difference in persistent OME at or before 1 month. NNT Not applicable
Persistent OME assessed with: tympanometry and otoscopy follow up: range 1 to 3 months № of participants: 580 (7 RCTs) ^{1,g}	RR 1.06 (0.92 to 1.22)	55.0%	58.3% (50.6 to 67.1)	3.3% more(NS) (4.4 fewer to 12.1 more)	 MODERATE ^b	In children with OME treated with antihistamines and/or decongestants compared with placebo there is probably no difference in persistent OME at 1-3 months. NNT Not applicable

Summary of findings:




19 Antihistamines and/or decongestants compared to placebo for otitis media with effusion

Patient or population: Children aged 5 months to 15 years with otitis media with effusion

Setting: Primary health care

Intervention: Antihistamines and/or decongestants (Studies used: chlorpheniramine & pseudoephedrine, ebastine, cinnarizine, oxymetazoline, phenylpropranolamine, phenylpropranolamine & brompheniramine, triprolidine & pseudoephedrine, phenylephrine, diphenhydramine & pseudoephedrine)

Comparison: Placebo

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Antihistamines and/or decongestants	With Antihistamines and/or decongestants	Difference		
Persistent OME assessed with: tympanometry and otoscopy follow up: range 3 to 12 months № of participants: 119 (2 RCTs) ^{1,h}	RR 1.24 (0.72 to 2.13)	27.3%	33.8% (19.6 to 58.1)	6.5% more (NS) (7.6 fewer to 30.8 more)	 LOW ^{b,c,i}	In children with OME treated with antihistamines and/or decongestants compared with placebo there is possibly no difference of OME after 3 -12 months. NNT Not applicable
Adverse effects (most commonly irritability, sedation and gastrointestinal upset) assessed with: parental report follow up: median 1 months № of participants: 1144 (6 RCTs) ^{1,j}	RR 2.70 (1.87 to 3.88)	6.4%	17.4% (12.0 to 25.0)	10.9% more (5.6 more to 18.5 more)	 MODERATE ^{b,k}	In children with OME treated with antihistamines and/or decongestants compared with placebo there are probably more adverse events. NNH ~10
Surgery required (tympanostomy, myringotomy) follow up: range 1 to 3 months № of participants: 295 (4 RCTs) ^{1,i}	RR 1.07 (0.81 to 1.41)	40.3%	43.2% (32.7 to 56.9)	2.8% more (NS) (7.7 fewer to 16.5 more)	 LOW ^{b,c,f}	In children with OME treated with antihistamines and/or decongestants compared with placebo there is possibly no difference in need for surgical interventions. NNT 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; MD: Mean difference

Summary of findings:

19 Antihistamines and/or decongestants compared to placebo for otitis media with effusion

Patient or population: Children aged 5 months to 15 years with otitis media with effusion

Setting: Primary health care

Intervention: Antihistamines and/or decongestants (Studies used: chlorpheniramine & pseudoephedrine, ebastine, cinnarizine, oxymetazoline, phenylpropranolamine, phenylpropranolamine & brompheniramine, triprolidine & pseudoephedrine, phenylephrine, diphenhydramine & pseudoephedrine)

Comparison: Placebo

Outcome No of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Antihistamines and/or decongestants	With Antihistamines and/or decongestants	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, Griffin 2011 (Cantekin 1991, Haugeto 1981a, Haugeto 1981b, O'Shea 1980)
- b. Inconsistency: Different treatment regimens used between studies.
- c. Imprecision: Small studies, Optimal informational size not reached
- d. Studies taken from: Cochrane Review, Griffin 2011 (O'Shea 1980)
- e. Studies taken from: Cochrane Review, Griffin 2011 (Cantekin 1983, Cantekin 1991, Fabian 1986, Haugeto 1981a, Haugeto 1981b, Hayden 1984, Saunte 1978)
- f. Risk of bias: risk selection bias (not clear in several studies), attrition bias (Saunte 1978, Hayden 1984) - however removal of these studies does not influence the outcome - not rated down.
- g. Studies taken from: Cochrane Review, Griffin 2011 (Choung 2008, Dusdieker 1985, Edstrom 1977, Fabian 1986, Hughes 1984, Lesser 1986, O'Shea 1980).
- h. Studies taken from: Cochrane Review, Griffin 2011 (Hughes 1984, O'Shea 1980)
- i. Indirectness: Noted to have wide range of time points for outcome, data converted from outcome measure of ears in meta-analysis. Not rated down.
- j. Studies taken from: Cochrane Review, Griffin 2011 (Cantekin 1983, Cantekin 1991, Fabian 1986, Lesser 1986, O'Shea 1980, Saunte 1978).
- k. Imprecision: Optimal information size not reached, but significant difference noted. Not rated down.
- l. Studies taken from: Cochrane Review, Griffin 2011 (Choung 2008, Fabian 1986, Hughes 1984, Saunte 1978)

References

1. Griffin G, Flynn CA. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. The Cochrane database of systematic reviews. 2011(9):Cd003423. Epub 2011/09/09. doi: 10.1002/14651858.CD003423.pub3. PubMed PMID: 21901683.