Evidence tables for review question: What interventions are effective for treating otorrhoea (ear discharge) after surgery for OME-related hearing loss in children under 12 years?

Table 4: Evidence tables

van Dongen, 2014

Bibliographic Reference	van Dongen, Thijs M A; van der Heijden, Geert J M G; Venekamp, Roderick P; Rovers, Maroeska M; Schilder, Anne G M; A trial of treatment for acute otorrhea in children with tympanostomy tubes.; The New England journal of medicine; 2014; vol. 370 (no. 8); 723-33

Study details

Country/ies where study was carried out	Netherlands
Study type	Randomised controlled trial (RCT)
Study dates	June 2009 - May 2012
Inclusion criteria	Children aged 1 to 10 years with tympanostomy tube otorrhoea for up to 7 days
Exclusion criteria	Body temperature >38.5°C, use of antibiotics during previous two weeks, history of tympanostomy tube placement within the previous two weeks, an episode of otorrhoea in the previous four weeks, three or more episodes of otorrhoea in the previous six months, four or more episodes of otorrhoea in the previous year, Down's syndrome, craniofacial anomaly, known immunodeficiency, and history of allergic reaction to study medications
Patient characteristics	N=230 (Hydrocortisone-bacitracin-colistin drops: N=76; Oral amoxicillin-clavulanate suspension: N=77; Initial observation: N=77) Mean age in years (SD):

	Hydrocortisone-bacitracin-colistin drops: 4.6 (2.1) Oral amoxicillin-clavulanate suspension: 4.4 (2.0) Initial observation: 4.4 (2.0) Sex (male/female): Hydrocortisone-bacitracin-colistin drops: 50/26 Oral amoxicillin-clavulanate suspension: 40/37 Initial observation: 43/34 Persistent otitis media with effusion: Hydrocortisone-bacitracin-colistin drops: N=40 Oral amoxicillin-clavulanate suspension: N=50 Initial observation: N=41 Recurrent acute otitis media: Hydrocortisone-bacitracin-colistin drops: N=36 Oral amoxicillin-clavulanate suspension: N=27 Initial observation: N=36
Intervention(s)/control	Hydrocortisone-bacitracin-colistin drops: administered as 5 drops, 3 times a day, in the discharging ear/ears for 7 days Oral amoxicillin-clavulanate suspension: 30 mg of amoxicillin and 7.5 mg of clavulanate per kg per day in three divided doses for 7 days Initial observation: observation for 2 weeks (no assigned medication prescription to fill)
Duration of follow-up	Children were assessed at 2 weeks and 6 months.
Sources of funding	Not industry funded
Sample size	N=230
Other information	Otorrhoea was assessed by otoscopy. The disease-specific health-related quality of life was assessed with the Otitis Media-6 (OM-6) questionnaire, and lower scores indicate better quality of life.

RCT: randomised controlled trial; SD: standard deviation

Outcomes

Hydrocortisone-bacitracin-colistin drops versus oral amoxicillin-clavulanate suspension versus initial observation: Otorrhoea, adverse effects of intervention and quality of life

Outcome	Hydrocortisone-bacitracin-colistin drops, N = 76	Oral amoxicillin-clavulanate suspension, N = 77	Initial observation, N = 77
Otorrhoea (the presence of otorrhoea; at 2 weeks) Custom value	4/76	34/77	41/75
Otorrhoea (recurrent episodes of otorrhoea; up to 6 months) Custom value	0/76	1/77	1/75
Adverse effects of intervention (local discomfort or pain during administration; up to 2 weeks) Custom value	16/75	0/77	-
Adverse effects of intervention (gastrointestinal discomfort; up to 2 weeks) Custom value	0/75	18/77	-
Adverse effects of intervention (rash; up to 2 weeks) Custom value	2/75	3/77	-
Adverse effects of intervention (oral candidiasis; up to 2 weeks) Custom value	0/75	0/77	-

Outcome	Hydrocortisone-bacitracin-colistin drops, N = 76	Oral amoxicillin-clavulanate suspension, N = 77	Initial observation, N = 77
Adverse effects of intervention (serious adverse events such as local cellulitis, perichondritis, mastoiditis, and intracranial complication; up to 2 weeks) Custom value	0/75	0/77	0/75
Quality of life (changes in the disease-specific health-related quality-of-life scores assessed with the OM-6 questionnaire; at 2 weeks) Median (IQR)	-1 (-14 to 11)	1 (-11 to 18)	0.5 (-15 to 26)

Critical appraisal - Cochrane RoB2

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Randomisation sequence generated by an independent data manager, and the allocation sequence was concealed. No significant differences between groups at baseline.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	High *(Participants and personnel were aware of intervention, and there were changes from assigned intervention: 2/76 in ear drops group, 6/77 in oral suspension group, and 15/77 in initial observation group. Appropriate analysis was used.)*

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(The data were available for 99% of participants for all outcomes.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low/High *(Methods of measuring the outcomes were appropriate, and no difference in measurement of the outcomes between intervention groups. Outcome assessors were aware of intervention status. Low risk for the presence of otorrhoea at 2 weeks as outcome measurement by otoscopy may not be influenced by knowledge of assigned intervention, and high risk for outcomes reported by parents, such as recurrent otorrhoea, adverse effects, and quality of life, as they may be somewhat subjective and may be influenced by knowledge of assigned intervention.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(There is clear evidence that all eligible reported results for the outcome correspond to all intended outcome measurements and analyses.)*
Overall bias and Directness	Risk of bias judgement	High *(The study is judged to be at high risk of bias in at least one domain.)*
Overall bias and Directness	Overall Directness	Indirectly applicable *(Population is indirect due to 43% of recurrent acute otitis media. Study was conducted from 2009 to 2012.)*
Overall bias and Directness	Risk of bias variation across outcomes	None

RoB: risk of bias