'Comparison of ototopical antibiotic-steroid drops or oral antibiotics versus watchful waiting in children with acute tympanostomy tube otorrhea'

Gepubliceerd: 06-10-2008 Laatst bijgewerkt: 18-08-2022

Current management of tympanostomy tube otorrhea includes ototopical antibiotic-steroid drops, oral antibiotics or watchful waiting. Empirical evidence regarding the cost-effectiveness of these approaches is lacking.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26909

Bron
NTR

Verkorte titel
N/A

Aandoening

Acute tympanostomy tube otorrhea.

Ondersteuning

Primaire sponsor: - Wilhelmina Children's Hospital
- Julius Center for Health Sciences and Primary Care

University Medical Center Utrecht
Overige ondersteuning: ZonMw, program effectiveness research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Otoscopic signs of otorrhea at the scheduled follow-up visit at 2 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Otorrhea is the most common complication in children with tympanostomy tubes in place.

In the Netherlands, each year about 10,000 children suffer from tympanostomy tube otorrhea (TTO). It causes discomfort to the child and is a cause of concern to its parents. Current management of TTO exists of ototopical antibiotic-steroid drops, oral antibiotics or watchful waiting. Empirical evidence regarding the cost-effectiveness of these approaches is lacking.

Research questions:

1. What is the effectiveness of oral antibiotics versus ototopical antibiotic-steroid drops versus watchful waiting in children with acute TTO in terms of otoscopic signs of otorrhea, days with ear discharge, recurrent episodes of TTO, adverse effects, and quality of life?

2. What is the relation between costs and effects of these interventions?

Study design:
Pragmatic multicenter randomized trial with a follow-up of 6 months.

Study population:
315 children aged 1 to 10 years developing otorrhea as from 2 weeks after insertion of tympanostomy tubes.

Intervention:
1) hydrocortison-bacitracine-colistine (Bacicoline-B) ear drops (3dd 5 drops for 7 days);
2) amoxicillin-clavulanic acid (30-7.5 mg/kg in 3dd to be taken orally for 7 days); 3) watchful waiting.

Primary outcome measure:
Otoscopic signs of otorrhea at 2 weeks follow-up.

Secondary outcome measures:
Episodes and days of otorrhea, health-related quality of life, adverse effects of study medication, complications, microbiology of otorrhea samples, and cost-effectiveness.

Data-analysis:
The effects of watchful waiting versus ototopical antibiotic drops versus oral antibiotics will be calculated as risk differences and risk ratios with 95% confidence intervals. Kaplan Meier curves for duration of ear discharge will be plotted, and differences tested with a log rank test. Quality of life data will be analyzed with analyses of variance (ANOVA). All analyses will be performed on an
intention-to-treat basis.

Economic evaluation:
Incremental cost-effectiveness ratios (iCERs) with 95% confidence intervals will be calculated, i.e. the costs for society to treat the number of patients needed to clinically cure one patient.

Time schedule:
February 2009-January 2011; 36 months.

Doel van het onderzoek

Current management of tympanostomy tube otorrhea includes ototopical antibiotic-steroid drops, oral antibiotics or watchful waiting. Empirical evidence regarding the cost-effectiveness of these approaches is lacking.

Onderzoeksopzet

February 2009 - January 2012; 36 months.

Onderzoeksproduct en/of interventie

Children whose parents have given informed consent will be randomly assigned to either:

1) Hydrocortison-bacitracine-colistine (Bacicoline-B) ear drops (3dd 5 drops for 7 days);

2)
Amoxicillin-clavulanic acid (30-7.5 mg/kg in 3dd to be taken orally for 7 days); 3) watchful waiting.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All children aged 1 to 10 years developing otorrhea after insertion of tympanostomy tubes.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Having had tympanostomy tubes inserted within the preceding 2 weeks;

2. Having used systemic or ototopical antibiotics within the preceding 2 weeks;

3. Having had a period of tympanostomy tube otorrhea within the preceding 2 weeks;

4. Having had ear discharge for more than one week;

5. Known allergy to hydrocortison-bacitracine-colistine ear drops or amoxicillin-clavulanic acid;

6. Down syndrome;

7. Cleft palate.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	315
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1421
NTR-old	NTR1481
Ander register	ZonMw : 80-82310-98-09036
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A