Pijnlijk Loopoor Therapie Studie

Gepubliceerd: 27-09-2017 Laatst bijgewerkt: 15-05-2024

We hypothesise that antibiotic-corticosteroid eardrops are non-inferior to oral antibiotics in resolving ear pain and fever at day 3 (72 hours after randomisation) in children aged 6 months to 12 years visiting their GP with AOMd and either ear pain...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Bacteriële infectieziekten
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23467

Bron
NTR

Verkorte titel
PLOTS (Pijnlijk LoopOor Therapie Studie)

Aandoening

- Bacteriële infectieziekten

Aandoening

Acute Otitis media with ear discharge

Otitis media acuta met een loopoor

Ondersteuning

Primaire sponsor: Sponsor: Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht
Overige ondersteuning: Subsidising party:
The Netherlands Organisation for Health Research and Development (ZonMw), Rational Pharmacotherapy 5th Open Call – grant no. 84801 5006

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The proportion of children without ear pain (ear pain score 0 on the 0-6 Likert scale) and fever (body temperature below 38.0°C) at day 3.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Around 15-20% of children with AOM present with ear discharge due to a spontaneous perforation of the eardrum (AOMd). Since oral antibiotics effectively reduce ear pain and/or fever in children with AOMd, current guidance recommends general practitioners (GPs) to consider oral antibiotics for these children. However, oral antibiotics put children at risk for adverse effects and increase the risk of antimicrobial resistance. In children with AOMd, the perforation of the eardrum provides an opportunity to instill topical antibiotics directly into the middle ear without exposing children to systemic side effects and putting less selective resistance pressure on bacteria. Evidence on its effectiveness in children with AOMd is, however, lacking. We hypothesise that antibiotic-corticosteroid eardrops are non-inferior to oral antibiotics in resolving ear pain and fever at day 3 (72 hours after randomisation) in children aged 6 months to 12 years visiting their GP with AOMd and either ear pain or fever or both.

Objective: To establish the clinical and cost-effectiveness of antibiotic-corticosteroid eardrops as compared with oral antibiotics in children with AOMd.

Study design: A primary care based, open, randomised controlled non-inferiority trial.

Study population: Children aged 6 months to 12 years whose parents are consulting their GP because of AOMd and either ear pain or fever or both.

Intervention: Children will be randomly allocated to either 1) hydrocortisone-bacitracin-colistin (Bacicoline-B®) eardrops, five drops, three times per day in the discharging ear(s) for 7 days or 2) amoxicillin suspension or tablets 50 mg per kilogram body weight per day, divided over three oral doses for 7 days.

Main study parameters/endpoints: The primary outcome is the proportion of children without ear pain and fever at day 3. Secondary outcomes are ear pain intensity/severity; fever intensity/severity; ear discharge; time to resolution of total symptoms; persistent eardrum perforation; middle ear effusion; adverse events; disease-specific quality of life; antibiotic consumption; AOM recurrences; costs and cost-effectiveness; antimicrobial resistance.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participants will be followed for a total of 3 months. This includes a baseline visit, a telephone call at day 3 and a follow-up visit at 2 weeks. Parents of participating children will be asked to record their child’s symptoms in a daily diary during the first 2 weeks and a weekly diary afterwards. At the baseline and the 2 weeks home visits, otoscopy and tympanometry (at 2 weeks only) will be performed and otorrhoeal, nasopharyngeal and faecal samples will be collected. At 3 months, a faecal sample will be collected. Data collection methods and associated burden to participants have been extensively discussed with our parent panel. The proposed methods were judged both feasible and acceptable by our parent panel and have been successfully applied in our previous trial.

Children allocated to eardrops will not be exposed to systemic adverse effects associated with oral antibiotics and may be at lower risk of developing antimicrobial resistance. A potential risk is that children may experience a prolonged disease course and might need subsequent treatment with oral antibiotics if antibiotic-corticosteroid eardrops appear to be inferior to oral antibiotics. We however do not anticipate large differences in treatment failures between the two active treatment groups given the difference (30%) observed between oral antibiotics and placebo or no treatment in previous trials.

The main risk of eardrops is potential ototoxicity. Although the hydrocortisone-bacitracin-colistin eardrops do not contain an aminoglycoside, there still is a risk. However, based on current available literature and recent data from the Netherlands Pharmacovigilance Centre, the risk of ototoxicity associated with the use of eardrops is considered at most similar but probably lower than the risk of ototoxicity related to the middle ear infection itself. Both the Dutch College of General Practitioners and the Dutch ENT Society have balanced benefits and risks of using these eardrops in children with an active middle ear infection and concluded that the (potential) benefits outweigh the risks. Current status: Ongoing (restart trial september 2021).

Doel van het onderzoek

We hypothesise that antibiotic-corticosteroid eardrops are non-inferior to oral antibiotics in resolving ear pain and fever at day 3 (72 hours after randomisation) in children aged 6 months to 12 years visiting their GP with AOMd and either ear pain or fever or both.

Onderzoeksopzet

Primary outcome: day 3

Secondary outcomes: 0-3 days, 2 weeks, 3 months

Onderzoeksproduct en/of interventie

Children will be randomly allocated to either 1) hydrocortisone-bacitracin-colistin (Bacicoline-B®) eardrops, five drops, three times per day in the discharging ear(s) for 7 days or 2) amoxicillin suspension or tablets 50 mg per kilogram body weight per day, divided over three oral doses for 7 days.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children aged 6 months to 12 years whose parents are consulting the GP with AOM and ear discharge in one or both ears (< 7 days duration) and either parent-reported ear pain in the previous 24 hours or fever (child's body temperature of > 38.0°C in the previous 24 hours as reported by parents or as measured by the GP during consultation) or both.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Children will be excluded from participation if they;

1. are systemically very unwell and requires immediate oral antibiotics or immediate hospitalisation (e.g. child has signs and symptoms of serious illness and/or complications such as mastoiditis/meningitis);

2. are at high risk of serious complications including children with known immunodeficiency other than partial IgA or IgG2 deficiencies, craniofacial malformation such as cleft palate, children with Down syndrome, previous ear surgery other than grommet insertion;

3. have grommets in place;

4. have a pre-existing perforation of the eardrum;

5. had a prior AOM episode (with or without ear discharge) in previous 28 days;

6. used oral antibiotics or topical antibiotics in previous 2 weeks;

7. have a known allergy or sensitivity to oral amoxicillin or hydrocortisone-bacitracin-colistin;

8. have already participated in this trial.

Onderzoeksopzet

Opzet

Fase onderzoek:	4
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	13-12-2017
Aantal proefpersonen:	350
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
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Ethische beoordeling

Goedgekeurd WMO

Datum:	27-09-2017
Soort:	Eerste indiening
Toetsingscommissie:	Medical Research Ethics Committees United (MEC-U) Postbus 2500 3430 EM Nieuwegein 088 320 8784 info@mec-u.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52979
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6535
NTR-old	NTR6723
EudraCT	2017-000332-34
CCMO	NL61395.041.17
OMON	NL-OMON52979

Resultaten