Pain Intensity Monitoring in Paediatric Otitis Media

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We hypothesise that a primary care-based multifaceted intervention aimed at optimising pain management will provide benefit over ‘care as usual’ in children with acute otitis media (AOM).

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28222

Bron
Nationaal Trial Register

Verkorte titel
PIM-POM

Aandoening

Acute otitis media, Children, Ear pain, Analgesics, General Practice

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU), Julius Center for Health Sciences and Primary Care
Overige ondersteuning: ZonMw, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mean ear pain score during the first 3 days after the initial visit to the GP as measured by the Wong-Baker FACES® Pain Rating Scale (WBS).

Toelichting onderzoek

Achtergrond van het onderzoek

Background and rationale:

Acute otitis media (AOM) is one of the most common illnesses, the second most frequent reason to visit a general practitioner (GP) and a prime indication for antibiotic prescription in children. Parents of children with AOM often seek medical support to ease their child's symptoms, typically ear pain and fever, and to shorten the illness duration. Management options for GPs to meet these demands are prescription of antibiotics and/or the advice to administer analgesics. Current evidence on the effectiveness of antibiotics in children with AOM shows that antibiotics generally have only marginal beneficial effects on AOM symptoms including ear pain. Therefore, adequate pain management is recognised as the cornerstone of paediatric AOM. Despite the explicit recommendations on the use of analgesics in the relevant guidelines, analgesics are often neither prescribed nor explicitly recommended to parents of children with AOM in daily practice. Suboptimal analgesic management may lead to unnecessary pain and discomfort for the child and sleepless nights and loss of days of work for their parents. Moreover, it may contribute substantially to GP reconsultations and (delayed) antibiotic prescriptions because of persisting AOM symptoms. Although the need for improved pain management is evident, studies to how and to what extent this can be achieved are lacking. We therefore propose a pragmatic cluster randomised controlled trial (RCT) to assess the effectiveness of a primary care-based multifaceted intervention aimed at optimising pain management in children with AOM as compared with 'care as usual'.

Research questions:

1. What is the clinical effectiveness of a primary care-based multifaceted intervention aimed at optimising pain management in children aged 6 months to 10 years with ear pain and GP-confirmed AOM as compared with 'usual care', in terms of reducing the mean ear pain score during the first 3 days after the initial visit to the GP as measured by the Wong-Baker FACES® Pain Rating Scale (WBS)?

2. What is the clinical effectiveness of a primary care-based multifaceted intervention aimed at optimising pain management in children aged 6 months to 10 years with ear pain and GP-confirmed AOM as compared with 'usual care', in terms of number of days with ear pain and ear pain severity, number of days with fever, proportion of children with ear pain at various time points (24 hours, 2 to 3 days, 4 to 7 days), GP reconsultations because of AOM,

(delayed) antibiotic prescriptions because of AOM, health-related quality of life of the child and its parents, parental days off work, days lost from nursery or school for children, complications of AOM including acute mastoiditis, meningitis and intracranial abscess, adverse effects of analgesics?

3. What is the cost-effectiveness of this primary care-based multifaceted intervention as compared with 'usual care', in terms of the additional cost per additional 1 point reduction in mean ear pain score during the first 3 days after GP consultation?

Design and setting:

A pragmatic cluster RCT in 30 general practices in the Netherlands with the primary care practice as the unit of randomisation.

Study population:

Inclusion criteria: children aged 6 months to 10 years presenting to their GP with ear pain resulting in a GP diagnosis of AOM.

Exclusion criteria: ventilation tubes in place, Down's syndrome, craniofacial malformations, known immunodeficiencies, renal failure/insufficiency, children that were previously included in the trial or who have a sibling that was included in the trial.

Randomisation and study-group assignment:

Participating general practices will be randomised by an independent statistician using a computerised minimisation strategy with a random component of 30%. Factors that will be taken into account are practice list size and age distribution of the registered patients in each practice to ensure equal numbers of practices and approximately equal numbers of patients in both treatment arms. The study physician will access a trial randomisation website to obtain the study-group assignment for participating general practices. The randomisation assignment will be concealed and cannot be predicted in advance of or during enrolment.

Interventions:

Participating general practices will be randomised to either the intervention arm or to the 'usual care' arm.
Intervention: A primary-care based multifaceted intervention consisting of: 1) a blended

learning targeted at general practitioners (GPs) (an internet-based training combined with a face-to-face visit with the study physician); 2) an interactive parent information leaflet; and 3) a prescription of paracetamol and ibuprofen to be filled by parents the same day.

In the blended learning GPs will be trained to a) address pain management during consultation by using effective communication skills; b) adhere to the 2014 guideline “AOM in children” and the 2007 “Pain Relief’ guideline issued by the Dutch College of General Practitioners which recommend a high dose paracetamol at fixed time intervals for the first three days, and a non-steroidal anti-inflammatory drug (NSAID) as add-on if needed; c) use an interactive leaflet during consultation; and d) prescribe paracetamol and ibuprofen (as add-on if needed).

Control: In the control group, the GPs will provide ‘care as usual’.

Antibiotics will be prescribed according to the discretion of the participating GPs in both groups. No specific instructions on antibiotic prescribing will be provided.

Follow-up and data collection:

Parents of participating children will be asked to keep a daily diary of ear related symptoms, medication use, doctor consultation, and time off school or nursery for the child, or work or education for the parents during 2 weeks. At baseline parents will complete a short questionnaire including questions on presenting symptoms. At baseline, 2, and 4 weeks parents will complete quality of life questionnaires, and at 4 weeks parents will fill out a productivity instrument. The number of reconsultations, (delayed) antibiotic prescriptions or other medications for AOM, and referrals to secondary care (including surgical procedures) will be extracted from the child’s GP medical record at 4 weeks.

Outcome measures:

Primary outcome:

The mean pain score during the first three days after the visit after the initial GP visit as measured by the WBS.

Secondary outcomes:

Number of days with ear pain and ear pain severity; number of days with fever; proportion of children with ear pain at various time points (24 hours, 2 to 3 days, 4 to 7 days); GP reconsultations because of AOM; (delayed) antibiotic prescriptions because of AOM; health-

related quality of life of the child and its parents; parental days off work; days lost from nursery or school for children; complications of AOM including acute mastoiditis, meningitis and intracranial abscess; adverse effects of analgesics; and costs.

Sample size calculation:

Calculations of the group size are based on a clinically relevant reduction in the mean ear pain score during the first 3 days after the initial visit to the GP. Based on a previous trial the mean ear pain score during the first 3 days is 3.735 (measured by a 1-10 numeric rating scale with a standard deviation of 1.888. We consider a 25% reduction of this mean ear pain score to be clinically relevant. With a two-sided threshold of 5% indicating statistical significance and with 80% statistical power, a minimum of 66 children per group is needed. The inflation factor for the cluster design is 1.75 assuming an ICC of 0.05 (for practice level) and a cluster size of 15 children. As such, the number of children that need to be included per group will be 115. To allow for a maximum of 10% loss to follow-up, we aim to randomise 250 children.

Statistical analysis:

All analyses will be primarily performed according to the intention-to-treat principle.

Clinical effectiveness analysis:

The effect of optimised pain management compared to ‘usual care’ on the primary outcome (mean ear pain score during the first 3 days after the initial GP visit) will be calculated with a linear mixed model. A random intercept will be included in the model to account for cluster randomisation and a residual covariance (i.e. GEE type) matrix will be included for repeated measurements (days 1, 2 and 3 after the initial GP visit). The amount of clustering will be estimated with an intraclass correlation. In a secondary analysis of the primary outcome we will use a linear mixed model without inclusion of the residual covariance matrix (i.e. not taking repeated measuring into account). The results will be reported as the mean ear pain scores over time with 95% confidence intervals, additionally the treatment effect (corrected difference between the two study groups) will also be reported with 95% confidence intervals.

We will compare dichotomous secondary outcomes with mixed logistic regression. Count variables will be compared using mixed Poisson regression. All analysis will be corrected for baseline variability between the two study groups. Additionally, we will correct for pre-specified potential confounders such as: age, sex, ill appearance, fever, history of recurrent AOM, antibiotic use, and nursery attendance; if there are enough participants to do so. The analysis for primary and secondary outcomes will be performed in three steps: (1) a crude

analysis with treatment only; (2) adjustment for baseline; (3) adjustment for baseline and pre-specified confounders.

Cost-effectiveness analysis:

In the primary analysis, incremental cost-effectiveness ratios will be calculated by dividing the estimated differences in costs by the differences in effects observed, i.e. the additional cost per additional 1 point reduction in mean ear pain score during the 3 days after the initial GP visit, for the optimised pain management strategy compared to the 'usual care' strategy. In the secondary analysis the additional cost per additional QALY gained will be estimated for the optimised pain management strategy compared to the 'usual care' strategy.

Doel van het onderzoek

We hypothesise that a primary care-based multifaceted intervention aimed at optimising pain management will provide benefit over 'care as usual' in children with acute otitis media (AOM).

Onderzoeksopzet

January 2015 – March 2016; 14 months

Onderzoeksproduct en/of interventie

Participating general practices will be randomised to either the intervention arm or to the 'usual care' arm.

Intervention: A primary-care based multifaceted intervention: 1) a blended learning targeted at general practitioners (GPs) consisting of an internet-based training combined with a face-to-face visit with the study physician; 2) an interactive parent information leaflet; and 3) a prescription of paracetamol and ibuprofen to be filled by parents the same day. In the blended learning GPs will be trained to a) address pain management during consultation by using effective communication skills; b) adhere to the 2014 guideline "AOM in children" and the 2007 "Pain Relief' guideline issued by the Dutch College of General Practitioners which recommend a high dose paracetamol at fixed time intervals for the first three days, and a non-steroidal anti-inflammatory drug (NSAID) as add-on if needed; c) use an interactive leaflet during consultation; and d) prescribe paracetamol and ibuprofen (as add-on if needed).

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Antibiotics will be prescribed according to the discretion of the participating GPs in both groups. No specific instructions on antibiotic prescribing will be provided.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children aged 6 months to 10 years presenting to their GP with ear pain resulting in a GP diagnosis of AOM according to the diagnostic criteria of the practice guideline “AOM in children” issued by the Dutch College of General Practitioners.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Ventilation tubes in place

• Down’s syndrome

• Craniofacial malformation such as cleft palate

• Known immunodeficiencies

• Renal failure/insufficiency

• Children that were previously included in the trial

• A sibling that was previously included in the trial

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	19-12-2014
Soort:	Eerste indiening

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	NL4781
NTR-old	NTR4920
Ander register	METC UMC Utrecht : 80-83910-98-13006 ZonMw

Resultaten