analgesic ear drops for children with acute otitis media

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23221

Source
Nationaal Trial Register

Brief title
OPTIMA

Health condition

Acute Otitis media

Sponsors and support

Primary sponsor: Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (ZonMw), approved 2020 - project number: 10060011910003

Intervention

Outcome measures

Primary outcome

The primary outcome is the mean parent-reported ear pain score (using a 0-10 validated numerical rating scale) over the first three days.

Secondary outcome

Secondary outcomes include proportion of children consuming antibiotic in the first 7 days, number of days with ear pain during follow-up (4 weeks), overall symptom burden in the first 7 days, oral and topical analgesic use in the first 7 days, number of GP reconsultations with/without subsequent antibiotic prescribing during follow-up, generic and disease-specific quality of life at the end of follow-up, adverse events during follow-up, complications of AOM during follow-up, cost-effectiveness, and parents' and GPs' views of treatment acceptability, usability and satisfaction (qualitative investigation).

Study description

Background summary

Rationale: Acute otitis media (AOM) is a common childhood condition and a major cause of primary care consultation and antibiotic prescribing. Ear pain is the most prominent symptom of AOM. Evidence of effectiveness for interventions to control the pain and reduce reliance on antibiotics is urgently needed. Recently, we showed that an educational intervention to improve pain management in children with AOM led to an increase in oral analgesic use, but this neither resulted in lower parent-reported ear pain scores nor less antibiotic use. Members from our study team also conducted a UK-based trial providing some evidence that analgesic ear drops can reduce ear pain and antibiotic consumption in children with AOM, but the trial was closed early due to medicine supply issues (a different medicine) resulting in the need for further high-quality evidence on their effectiveness.

Objective: To investigate whether analgesic ear drops as added to usual care (oral analgesics with/without antibiotics) provide superior ear pain relief over 'care as usual' in children presenting to primary care with AOM and ear pain.

Study design: Pragmatic, two arm, individually randomised, open, superiority trial with cost-effectiveness analysis and nested qualitative investigation in general practices in the Netherlands with a follow-up of 4 weeks.

Study population: Children aged 1-6 years with a general practitioner(GP)-diagnosis of AOM and ear pain. Main exclusion criteria: children with (suspected) non-intact tympanic membrane (perforation or tubes) with/without otorrhoea including children with ear wax which hampers accurate tympanic membrane assessment upon otoscopy, those who are very unwell or require hospital admission, children who are at high risk of serious complications or have a known allergy or sensitivity to study medicine or similar substances.

Intervention: Children will be randomly allocated to either 1) Lidocaine ear drops (Otalgan®) 1-2 drops up to six times daily for a maximum of 7 days with usual care or 2) usual care. The study physician will not provide management advice other than instructions about the use of analgesic ear drops to parents of children randomly allocated to the intervention

group. All other management decisions, i.e. antibiotic prescribing and advice on oral analgesic use, will be left to the discretion of the GP in both groups (which will have been decided prior to the study visit).

Main study parameters/endpoints: The primary outcome is the mean parent-reported ear pain score (using a 0-10 validated numerical rating scale) over the first three days. Secondary outcomes include proportion of children consuming antibiotic in the first 7 days, number of days with ear pain during follow-up (4 weeks), overall symptom burden in the first 7 days, oral and topical analgesic use in the first 7 days, number of GP reconsultations with/without subsequent antibiotic prescribing during follow-up, generic and disease-specific quality of life at the end of follow-up, adverse events during follow-up, complications of AOM during follow-up, cost-effectiveness, and parents' and GPs' views of treatment acceptability, usability and satisfaction (qualitative investigation).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
All study participants will receive usual care. The potential benefits of study participation for those randomly allocated to the intervention group are symptom relief - including a reduction in ear pain - resulting from the use of analgesic ear drops and subsequently fewer GP repeat visits and antibiotic consumption.
Lidocaine ear drops (Otalgan®) are widely available in the Netherlands over-the-counter. These drops should not be used in children with a non-intact tympanic membrane (e.g. rupture/perforation or ventilation tube) due to the associated risk of tinnitus and deafness. We will exclude those children from study participation as well as those with ear wax which hampers accurate assessment of the tympanic membrane upon otoscopy. Topical application of lidocaine (in the ear) leads to very low systematic exposure. The only reported side-effect in the Summary of Product Characteristics of Otalgan® is hypersensitivity reaction (rare; <1/1,000). Based on these considerations, we judge our trial as negligible risk study.

Study objective

This is a superiority trial testing the hypothesis that analgesic ear drops as added to usual care (oral analgesics with/without antibiotics) provide superior ear pain relief over usual care in children aged 1 to 6 years with a GP-diagnosis of AOM and ear pain.

Study design

primary outcome: 3 days

secondary outcomes: 7 days, 4 weeks

Intervention

Children will be randomly allocated to either 1) Lidocaine ear drops (Otalgan®) 1-2 drops up to six times daily for a maximum of 7 days with usual (oral analgesic with/without antibiotics) care or 2) usual care

Contacts

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Eligibility criteria

Inclusion criteria

- Age 1 to 6 years
- GP-diagnosis of (uni- or bilateral) AOM
- Parent-reported ear pain in 24 hours prior to enrolment

Exclusion criteria

- Children with (suspected) non-intact tympanic membrane (perforation or tubes) with/without otorrhoea, including children with ear wax which hampers accurate tympanic membrane assessment upon otoscopy.
- Children who are systemically very unwell or require hospital admission (e.g. child has signs and symptoms of serious illness and/or complications such as mastoiditis/meningitis).
- Children who 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, Down syndrome and previous ear surgery
- Children who have a known allergy or sensitivity to study medicine or similar substances, e.g. other amide-type anesthetics (such as bupivacaine, mepivacaine and prilocaine)
- Children who have taken part in any research involving medicines within the last 90 days, or any other AOM-related research within the last 30 days.
- Children who need to continue taking other medicinal products containing lidocaine
- Children who have proven alternative source(s) of pain other than, and more severe than, the ear symptoms with which they are presenting.

- Children who have already participated in this trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9500
Other	ABR number: 77733 : EudraCT number: 2021-003019-24

Study results