Effectiveness of analgesic ear drops as add-on treatment to oral analgesics in children with acute otitis media: a pragmatic randomised controlled trial

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Middle ear disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON54000

Source
ToetsingOnline

Brief title
analgesic ear drops for children with acute otitis media (OPTIMA)

Condition

- Middle ear disorders (excl congenital)
- Ancillary infectious topics

Synonym
acute middle ear infection, acute otitis media

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: acute otitis media, analgesic ear drops, children, ear pain

Outcome measures

Primary outcome

The primary outcome is the mean parent-reported ear pain score over the first 3 days, using a 0-10 validated numerical rating scale.

Secondary outcome

Secondary outcomes include: proportion of children using antibiotics, oral analgesic use and overall symptom burden in the first 7 days; number of days with ear pain, number of GP reconsultations and subsequent antibiotic prescribing, adverse events, complications of AOM and cost-effectiveness during 4-week follow-up; generic and disease-specific quality of life at 4 weeks; parents* and GPs* views on treatment acceptability, usability and satisfaction (nested mixed methods process evaluation).

Study description

Background summary

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 introduction of an educational intervention to improve pain management in children with AOM resulted in an increase in oral analgesic use, but failed to impact on parent-reported ear pain or antibiotic use. A

UK-based trial run by study team members recently provided some evidence that analgesic ear drops can reduce ear pain and antibiotic consumption in children with AOM. This trial was closed early due to operational issues which leaves the question on the effectiveness of these drops.

Study objective

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

Study design

Pragmatic, two arm, individually randomised, open, superiority trial with cost-effectiveness analysis and nested mixed methods process evaluation in general practices in the Netherlands with a follow-up of 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 in addition to usual care or 2) usual care.
Treatment decisions as per usual care, i.e. antibiotics and oral analgesics, will be to the GP*s discretion in both groups. To those allocated to the intervention group, the study physician will not provide any treatment advice other than instructions about the use of analgesic ear drops.

Study burden and risks

All study participants will receive usual care. The potential benefits of study participation for those randomly allocated to the intervention group are better local symptom (ear pain) control and subsequently fewer repeat GP visits and antibiotic use .
Lidocaine ear drops (Otalgan®) are widely available over-the-counter in the Netherlands. These drops should not be used in children with a tympanic membrane perforation or ventilation tube as they carry a risk of inner ear damage causing hearing loss or tinnitus. These children will therefore be excluded, as well as those with ear wax obscuring visualisation of the tympanic membrane. Systemic exposure to lidocaine is very low when administered topically to the ear. The only reported side-effect in the Summary of Product Characteristics of Otalgan® is hypersensitivity reaction (rare; <1/1,000). We therefore judge this study as having a negligible risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

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

Exclusion criteria

Children:
- with (suspected) tympanic membrane perforation or ventilation tubes
- with ear wax obscuring visualisation of the tympanic membrane
- 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).
- who are at high risk of serious complications including children with known immunodeficiency other than partial IgA or IgG2 deficiencies, craniofacial malformation including cleft palate, Down syndrome and previous ear surgery (with the exception of ventilation tubes in the past).
- who have a known allergy or sensitivity to study medication or similar substances (e.g. other amide-type anaesthetics, bupivacaine, mepivacaine, prilocaine)
- 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.
- who suffer from chronic recurrent pain of another origin than the ear.
- who have participated in this trial during prior AOM episode.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2021
Enrollment:	300
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Otalgan
Generic name:	lidocaine hydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-07-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-08-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-03-2023
Application type:	Amendment
Review commission:	METC NedMec

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
EudraCT	EUCTR2021-003019-24-NL
Other	Netherlands Trial Register, ID: NL9500
CCMO	NL77733.041.21