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Ear wax removal in young children

Submission date
15/03/2018

Recruitment status
No longer recruiting

Registration date
29/03/2018

Overall study status
Completed

Last Edited
28/06/2019

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and Study Aims:
Ear wax is common in young children and can cause loss of hearing or prevent clinicians from adequately seeing the ear drum. Viewing the ear drum is essential to diagnose middle ear infections, which are more common in young children. Although this is a common problem, there have been no studies that compare different methods of wax removal. This study compares how well different methods remove wax

Who can participate?:
Well or ill boys and girls from 6 months through 5 years of age are eligible to participate if at least one ear has wax blocking ≥25% of the view of the ear drum.

What does the study involve?:
Children will be randomly assigned by a computer program to receive one of four wax removal treatments: a metal curette and three different irrigation methods which wash the wax out with squirts of water. Only ears that have blocking of ≥25% of the view of the ear drum will be cleaned. If a child has two blocked ears the same treatment will be used on each. Each procedure will take less than 15 minutes.

What are the possible benefits and risks of participating?
Children participating in this study will have the benefit of removal of ear wax which can decrease hearing and prevent diagnosis of ear infections. The risks of these procedures include minor scratches and abrasions to the ear canal, temporary discomfort and in rare cases rupture of the ear drum.

Where is the study run from?
This study will occur at the Primary Care Center of Children's Hospital of Pittsburgh.

How long will the study run?
This study will begin enrolling children January 6, 2016 and end August 10, 2016. We funded this study with our own division funds.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRO16040232

Study information

Scientific Title
In young children, what is the comparative effectiveness of three irrigation methods and curetting for removal of cerumen?

Study objectives
There are no comparative studies of various methods of cerumen removal. We sought to determine the effectiveness and feasibility of four methods of cerumen removal in young children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the University of Pittsburgh, 06/20/16, PRO16040232.

Study design
Single-center single-blind randomized parallel-assignment trial

Primary study design
Interventional

Secondary study design

Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Cerumen impaction

Interventions
After obtaining written informed consent, children were randomized to one of four treatment groups:
1. Irrigation using a 60-ml syringe with attached angiocath tubing
2. Irrigation using the Elephant Ear Washer Bottle System® (Miller Drug, Bangor, Maine)
3. Irrigation using the OtoClear Spray Wash Kit® (Bionix Medical Technologies, Toledo, Ohio)
4. Metal curette (Buck Ear Curette, 1.5mm, Bausch and Lomb, Bridgewater, New Jersey).
If a child had ≥25% cerumen occlusion in both ears the same procedure was used for each ear. Ears with ≤24% occlusion were not cleaned. It was not possible to blind subjects or parents to treatment assignment, but we blinded clinicians who assessed cerumen occlusion before and after cleaning. We randomized children using computer-generated blocks of four to generate equal treatment allocation within the following age strata: 6-23 months, 24-47 months, and 48-71 months. Treatment assignment was only revealed after consent was signed.
Curetting (CU) was performed by an experienced clinician using a metal curette using the technique described by Shaikh, et al. Irrigation was performed by a medical assistant or nurse using a syringe with angiocath tubing (SA), Elephant Ear Washer Bottle System® (EE), or OtoClear Spray Wash Kit® (OC). We did not pretreat with a cerumenolytic because there is no apparent benefit over water. For the SA procedure, we used a 60-m;l syringe coupled by Luer lock to a 23-gauge angiocath tubing cut off at 1.5 centimeters (cm). The needle and excess tubing were discarded. This length was chosen for safety because the average length of the external auditory canal in a newborn is 1.68 cm. The syringe was filled with warm water and a single stream of water was expressed through the angiocath tubing into the ear canal. The EE and OC systems are FDA-approved squirt-bottle irrigation systems with hand-held squeeze triggers that were attached to reservoirs filled with 420 ml of warm water. The EE is equipped with 2 cm catheter-like tips that we cut to 1.5 cm to deliver a single stream of water into the ear canal. The OC delivers water via a plastic tip shaped like an ear speculum with three angled holes to direct streams to the walls of the ear canal. All irrigation methods allowed water, cerumen, and debris to continuously exit the ear canal. The medical assistant or nurse performing irrigation inspected the ear canal using an otoscope after approximately 100 ml, after removal of a large piece of wax, or if the child needed a break. After irrigation, the ear canal was dried by tipping the child’s head allowing drainage out of each ear. If moisture remained, a tissue was twisted to form a wick, and gently inserted into the canal.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary outcome was the reduction in cerumen occlusion. A clinician, blinded to the treatment assignment, characterized the wax and determined the percent cerumen occlusion before and after cleaning. We categorized cerumen occlusion into 5 categories: 0%, 1-24%, 25-49%, 50-74%, 75-99%, and 100%. Successful cerumen removal was defined as ≤24% occlusion after the procedure.

Secondary outcome measures
1. Time until completion
2. Number of personnel and level of training required to complete the procedure. We recorded the number of personnel and level of training (parents, students, medical assistants, nurses, and physicians) required to position the child, complete the procedure, and perform cleanup.
3. Parental satisfaction. After the procedure, we queried the parents, using a 10-point scale, how scary the experience was for their child, how painful the experience was for their child, how their child tolerated the experience, if they would want this procedure done again, how easy the experience was, how they felt about the time it took, and how satisfied they were with their experience.

Overall study start date
26/04/2016

Completion date
02/02/2018

Eligibility

Key inclusion criteria
1. Attended Children's Hospital of Pittsburgh Primary Care Center between June and August 2016
2. Health or sick
3. Aged 6 months to 6 years
4. Cerumen occluding ≥25% of at least one tympanic membrane by otoscopy

Participant type(s)
Mixed

Age group
Child

Lower age limit
6 Months

Upper age limit
6 Years

Sex
Both

Target number of participants

Pilot study: as many children as could be enrolled in a two-month window of availability of the research assistant

Total final enrolment
38

Key exclusion criteria
1. Otorrhea
2. Uses hearing aids
3. History of tympanic membrane perforation, tympanostomy tubes, or otitis externa in the previous 2 weeks.

Date of first enrolment
01/06/2016

Date of final enrolment
10/08/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Children's Hospital of Pittsburgh Primary Care Center Oakland
United States of America
15213

Sponsor information

Organisation
University of Pittsburgh Institutional Review Board

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Sponsor type
University/education

ROR

https://ror.org/01an3r305

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We intend to submit results for publication as soon as we have registered this trial.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/06/2019	28/05/2019	Yes	No