

# Ear wax removal in young children

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| <b>Submission date</b><br>15/03/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>29/03/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>28/06/2019       | <b>Condition category</b><br>Ear, Nose and Throat | <input type="checkbox"/> 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  $\geq 25\%$  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  $\geq 25\%$  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?

Timothy R. Shope, MD, MPH  
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# Contact information

## Type(s)

Scientific

## Contact name

Dr Timothy Shope

## Contact details

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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  $\geq 25\%$  cerumen occlusion in both ears the same procedure was used for each ear. Ears with  $\leq 24\%$  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.

Curettage (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-ml 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  $\leq 24\%$  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  $\geq 25\%$  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

**Sponsor details**

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**Sponsor type**

University/education

ROR

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 06/06/2019   | 28/05/2019 | Yes            | No              |