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The use of wax softeners (ceruminolytics) before dewaxing: a randomised clinical study

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 20/12/2013	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0264191670

Study information

Scientific Title

Study objectives
Does the use of wax softening agents immediately prior to dewaxing by microsuction improve the pain or discomfort of the procedure for the patient?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ear, Nose and Throat: Ear dewaxing

Interventions
Selected patients will be given an information sheet as well as having the procedure and study explained to them in a private clinic room and then asked to give written consent by the clinician or nurse performing the dewaxing.

The dewaxing will be performed by the usual clinic staff comprising of specialist nurses and ENT doctors, including the researchers.

Up to one hour will be allowed to decide whether or not they would like to participate.

Patients who give consent will have each ear randomised to one of two groups using an opaque envelope:
1. Group A will have the ear cleaned without any ear drop softeners
2. Group B will have 5 drops of sodium bicarbonate ear drops instilled into the canal 10 minutes prior to cleaning.

A total of 70 ears in each group will be required. Most patients tend to need both ears dewaxing but not invariably, therefore the total number of patients in the study will be between 70 and 140.

The decision to use sodium bicarbonate is based on the fact that the literature suggest there is little difference in the effectiveness of different cerumenolytic agents. Sodium bicarbonate is the most commonly used agent for this scenario in the region and is cheap and safe.

If a patient is to have sodium bicarbonate, this will be given while the patient is waiting to have the procedure done. There is often a very short wait in these clinics and giving the drops at this point will minimise the time delay incurred by the patient. Although a patient may have their ears in different treatment groups, they will be dewaxed at the same time always starting with the right ear (if both ears being done).

The dewaxing procedure will be timed for each ear.

After having had the procedure the patient will be given a sheet with visual analogue scale for the degree of discomfort or pain sustained. The clinician will also fill in his/her part of the form with regard to the ease of performing the technique, the time taken and any complications that had occurred. These forms will be filled out for each ear.

It is not possible to blind either the patient or the clinicians as both will be aware of ear drops in the external ear canal.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ceruminolytics

Primary outcome measure
Visual analogue scores for pain and discomfort for patient.

Secondary outcome measures
1. Time taken to perform procedure
2. Visual analogue score for ease of procedure for clinician

Overall study start date
02/01/2007

Completion date
02/06/2007

Eligibility

Key inclusion criteria
Patients who, by the decision of the examining clinician, need to undergo dewaxing.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
140

Key exclusion criteria
1. Unable to provide informed consent
2. Any infected ears

Date of first enrolment
02/01/2007

Date of final enrolment
02/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research and Effectiveness Department
Bristol
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
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Sponsor type
Government

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http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration