

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
28/09/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
28/09/2007	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
20/12/2013	Ear, Nose and Throat	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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)

ceruminolitics

Primary outcome(s)

Visual analogue scores for pain and discomfort for patient.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

C/O Research and Effectiveness Department

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration