

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

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

**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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BS2 8HW

**Sponsor information****Organisation**

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

**Sponsor details**

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**Sponsor type**

Government

**Website**

<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