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Pre-treatment drops or spray for managing earwax

Submission date
28/10/2024

Recruitment status
No longer recruiting

Registration date
23/12/2024

Overall study status
Ongoing

Last Edited
01/08/2025

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Earwax is a naturally occurring substance that forms part of the ear's self-cleaning mechanism. Normally it causes no problems however earwax can build up in the ear canal and become dry and impacted. This build-up could be due to overproduction of earwax, use of cotton buds or reduced self-cleaning mechanism due to age. Excessive earwax causes problematic symptoms such as hearing loss, pain and dizziness and can have a significant negative impact on quality of life. It is thought to affect 2.3 million people per year in the UK.
Earwax that is causing symptoms should be removed as recommended in healthcare guidelines. Earwax can be removed mechanically but research has shown that wax should be softened first to ease its removal and reduce the chances of discomfort. This is done by the use of wax softeners. Many different wax softeners are available but the most commonly used is olive oil. The Audiology service at BCUHB offers a wax removal service ran by Audiology practitioners for patients in North Wales in Primary Care locations. Patients can self-refer or be referred by a GP or other healthcare professional for wax removal. Currently patients are advised to use either olive oil drops or olive oil spray for 7 days prior to their wax removal appointment.
Many previous research studies have previously compared the use of different wax softeners but none have compared different delivery methods (drops or spray). We aim to do this by randomly allocating GP practices that offer the wax removal pathway to either using olive oil spray or olive oil drops prior to their wax removal appointment and comparing the outcomes between the two groups. The outcomes we will investigate are the success of wax removal by microsuction, rate of adverse events and improvement in self-reported symptoms following wax removal.

Who can participate?
Adult patients aged 18 years old or over attending the BCUHB Audiology Primary Care wax removal service delivered in GP Practices across North Wales.

What does the study involve?
Each GP practice delivering the BCUHB Audiology Primary Care wax removal service will be randomly assigned to instruct their patients to use either olive oil drops or olive oil spray for 7 days before attending their wax removal appointment. As per current service delivery patients will be responsible for purchasing/sourcing and administrating the olive oil solution themselves.

Patients will then attend their wax removal appointment with the Audiology Practitioner. At the appointment patients will be asked about the symptoms they are experiencing in relation to the wax in their ears. The Audiology Practitioner will then attempt to remove the earwax with microsuction. Following microsuction the Audiology Practitioner will ask the patient to:
1. Rate the improvement in the symptoms they reported at the start of the appointment
2. Record the amount of wax remaining in the patient's ear/s
3. Arrange another appointment for wax removal if it hasn't been fully successful.
The study will be looking at comparing the above outcomes between the two groups (olive oil drops and olive oil spray) to see whether there are any differences.
All data recorded as part of the study is currently being recorded as part of service evaluation and no patient identifiable information will be collected.

What are the possible benefits and risks of participating?
Taking part in the study may not directly benefit the patient but the research will hopefully help us understand whether the method of delivering olive oil to the ear has any difference on the outcome of wax removal. There are no known associated risks to the patient and also participating in the study does not affect the patient's normal clinical care in any way.

Where is the study run from?
Betsi Cadwaladr University Health Board (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Linor Llwyd Jones, linor.ll.jones@wales.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mrs Linor Jones

Contact details
Audiology Department
Glan Clwyd Hospital
Rhyl
United Kingdom
LL18 5UJ
+44 (0)3000843864
Linor.Ll.Jones@wales.nhs.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
316799

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A comparison of the effectiveness of pre-treatment olive oil used as drops versus spray prior to earwax removal by microsuction

Study objectives
Olive oil spray is more effective than olive oil drops when used as a pre-treatment wax softener prior to wax removal by microsuction.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/07/2024, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8150; riverside.rec@hra.nhs.uk), ref: 24/LO/0420

Study design
Single-centre two-arm parallel-group interventional cluster randomized control trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Pre-treatment of wax in patients accessing a wax removal service

Interventions
The research study is a two-arm cluster randomised control trial. The clusters refer to GP practices and the two arms refer to the pre-treatment of olive oil drops and olive oil spray. The pre-treatment of choice will be randomised to the GP practices prior to the start of the study. The randomisation will involve assigning to either olive oil spray or olive oil drops to the practice in a prior allocation.

The research is a between-subjects design with one factor (olive oil delivery method) and two levels (olive oil drops and olive oil spray). As per normal clinical care patients will source and administer the olive oil themselves. Patients will be recommended to apply three drops or three sprays of olive oil every day for 7 days as per current BCUHB Audiology Primary Care wax removal service guidelines as stated by the Welsh Government 'Ear Wax Management Primary and Community Care Pathway'.

Randomisation will happen at the GP surgery (cluster) level with a 1:1 allocation ratio to olive oil drops or olive oil spray using stratified block randomisation based on prognostic value. Stratifying based on site size (small, large) using block sizes 2 and 4. Randomisation will be done using randomisation software.

Intervention Type
Device

Pharmaceutical study type(s)
Medical device - olive oil

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Olive oil drops, olive oil spray

Primary outcome measure
The success and effectiveness of wax removal will be measured by comparing the proportion of patients where wax removal is successful at the first attempt, not needing a further visit, with those who need another visit for a re-attempt at removal. This is determined by the Audiology Practitioner immediately after microsuction.

Secondary outcome measures
1. Self-reported needs and symptoms assessed immediately following wax removal. The wax removal pathway is a needs-based pathway and each patient being seen for wax removal is asked about their main need/symptom for accessing the service. These needs/symptoms are documented by the Audiology Practitioner. Following the wax removal, the Audiology Practitioner asks the patient to rate how much improvement there is in their reported need /symptom on a five-point scale (much better, slightly better, about the same, slightly worse, much worse).
2. Post-microsuction visualisation ratings for the two groups as rated on an analogue scale immediately after microsuction is complete, assessed using the ratings below:
0 No or very minimal earwax, complete visualisation of tympanic membrane
1 Minor amount of earwax with majority of tympanic membrane visible
2 Moderate amount of earwax with only part of the tympanic membrane visible
3 Fully occluding wax, no visualisation of tympanic membrane

3. Adverse events of microsuction recorded as per normal clinical practice, any that occur in clinic during or immediately after microsuction and any reported by patients up to 1 week after microsuction.

Overall study start date
31/01/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Adults over 18 years of age
2. Able to give informed consent for microsuction
3. Presence of wax in one or both ears giving rise to symptoms or need that warrant removal

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1742

Key exclusion criteria
1. Under 18 years of age
2. Active ear infection
3. Active dermatitis
4. Perforated or non-intact tympanic membrane
5. Foreign body present in ear canal
6. Any contraindication for microsuction or use of wax softeners – previous ear surgery including mastoid obliteration; grommets in situ

Date of first enrolment
01/11/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

Sponsor details
R&D Department
Holywell Community Hospital
Holywell
Wales
United Kingdom
CH8 7TZ
+44 (0)3000 856753
laura.longshaw@wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://bcuhb.nhs.wales/services/hospital-services/research-and-development/

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The researcher is hoping to share the findings following the completion of this study at a national level by publication in a peer-reviewed journal and at a national conference. The findings will be shared within the field of Audiology and further within general healthcare networks. It is also hoped that the findings will be shared with NICE to supplement future recommendations for wax management.

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-public available repository - internal BCU Audiology Sharepoint online (restricted access).
The datasets generated during and/or analysed during the current study are not expected to be made available due to NHS legislation.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available