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An evaluation of the self-use of bulb syringes for the self-treatment of ear wax and their impact on primary care workload - a randomised controlled trial

Submission date
07/09/2005

Recruitment status
No longer recruiting

Registration date
29/09/2005

Overall study status
Completed

Last Edited
18/07/2011

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

Study information

Scientific Title

Acronym
Bulb syringe study

Study objectives
Ear wax is a commonly presenting problem in primary care. It is surprisingly under-researched and as background to this study we have previously undertaken two pilot studies - a questionnaire study and a feasibility study.
Ear wax is commonly treated by syringing the ear and syringing has been shown to improve hearing and symptoms. However, most GPs have increasingly delegated managing ear wax to practice nurses. The annual salary costs of practice nurses undertaking ear syringing in UK general practice have been estimated at about £8 million. Could that time be better spent? Achieving current NHS targets (such as the New GP Contract) has significant workload implications. Patients do not like delays associated with treating ear wax and patients, GPs and practice nurses would like to encourage such self-help. In some countries plastic bulb syringes with which to irrigate the ear are widely available. Such devices could potentially be marketed in the UK. Their availability in the UK and evidence of their effectiveness and safety could both reduce demands on health service resources and satisfy patients' demands for rapid relief of symptoms. Preliminary results of the pilot study suggest bulb syringes are effective, safe and acceptable to patients.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ear wax

Interventions
Self-treatment using a bulb syringe compared with the standard treatment of syringing by a practice nurse or GP.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Objective clearance of wax
2. Relief of symptoms
3. Acceptability of treatment
4. Unwanted effects of treatment
5. Proportion of people requiring further intervention within 6 weeks
6. Costs of prescriptions for subsequent ear care in 6 weeks from randomisation

Secondary outcome measures
Rates of consultation with GP and practice nurse for ear care at one and two years.

Overall study start date
01/02/2004

Completion date
31/01/2007

Eligibility

Key inclusion criteria
Adults presenting at participating surgeries with symptoms of ear wax and having wax occluding one or both ear drums.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
236

Key exclusion criteria

History of perforated ear drum, other significant ear disease or surgery, signs of perforation or infection in the affected ear, patients with cognitive impairment sufficient to preclude them from following the instructions or completing the questionnaire.

Date of first enrolment
01/02/2004

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Overton Surgery
Overton
United Kingdom
RG25 3DZ

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Research Support Office
Building 37
Room 4033
University of Southampton
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

Website
http://www.soton.ac.uk

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
University/education

Funder Name
Royal College of General Practitioners Scientific Foundation Board, SFB/2003/32 (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2008		Yes	No
Results article	results	01/03/2011		Yes	No