

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/07/2011	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 hypothesis

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

Condition

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

Overall study end date

31/01/2007

Eligibility**Participant 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

Participant 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.

Recruitment start date

01/02/2004

Recruitment end date

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