Effect of piston diameter in stapedotomy for otosclerosis: a randomized controlled trial.

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The primary objective of this study is to evaluate the effectiveness of two differently sized pistons used in primary stapedotomy for otosclerosis in terms of hearing improvement, complication rate and general and disease-specific quality of life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Middle ear disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON38574

Source
ToetsingOnline

Brief title
PISTON

Condition

- Middle ear disorders (excl congenital)

Synonym
ossification, Otosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Otosclerosis, Piston, RCT, Stapedotomy

Outcome measures

Primary outcome

Primary outcome measure is postoperative air-bone gap closure on pure-tone audiometry at 12 months follow-up.

Secondary outcome

Secondary outcome measures are hearing improvement on pure-tone and speech audiometry, disease-specific and general quality of life and complications (with specific attention for tinnitus and vertigo).

Study description

Background summary

Otosclerosis is characterized by bony deposits in the middle ear, resulting in stapes fixation and progressive hearing loss. It can be treated effectively by surgically removing (part of) the stapes and replacing it with a prosthesis/piston. Since Shea first introduced stapes surgery as a treatment option for otosclerosis in 1956, a large number of prostheses or pistons have been developed. Shape, size and type of material have been the main focus in enhancing pistons. The piston shaft diameter ranges from 0.3 mm up to 0.8 mm. Available evidence from clinical studies, mathematical models and temporal bone studies suggests that a larger diameter piston is associated with better hearing outcomes. However, a lack of high quality, clinical studies precludes firm evidence based recommendations.

Study objective

The primary objective of this study is to evaluate the effectiveness of two differently sized pistons used in primary stapedotomy for otosclerosis in terms of hearing improvement, complication rate and general and disease-specific quality of life.

Study design

Single-blinded randomized controlled trial. Both patients and audiologists are blinded.

Intervention

Primary stapedotomy, either with a 0.4 mm piston or a 0.6 mm piston.

Study burden and risks

Compared to routine clinical practice, the study requires that half of the participants receive a 0.6 mm diameter piston instead of a 0.4 mm diameter piston. A larger diameter piston might be more beneficial based on the available evidence with regards to hearing outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age * 18 years;
Otosclerosis based on a clinical history of progressive hearing loss and pure-tone audiometry showing conductive hearing loss with an air-bone gap > 20 dB nHL in the range of 500, 1000, 2000 and 4000 Hz;
Eligible for stapedotomy;
Willingness and ability to participate in all scheduled procedures outlined in this research protocol;
General health allowing general anesthesia;
Good understanding of the Dutch language.

Exclusion criteria

Previous middle ear surgery;
Known aberrant (middle ear) anatomy in one or both ears;
Co-morbid middle or inner ear pathology, osteogenesis imperfecta, an active ear infection in one or both ears or active otosclerosis with Schwartze sign;
Disability that could interfere with audiologic evaluation and/or questionnaire fulfillment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	13-03-2014
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	Piston
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28170
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45622.041.13
OMON	NL-OMON28170