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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28170

Source
Nationaal Trial Register

Brief title
PISTON

Health condition

Otosclerosis; stapedotomy; stapes surgery.

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: University Medical Center Utrecht (UMCU)

Intervention

Outcome measures

Primary outcome

Postoperative air-bone gap closure at twelve months postoperatively, as measured by pure-tone audiometry for the following frequencies: 500, 1000, 2000 and 4000 Hz, in accordance to the Committee on Hearing and Equilibrium guidelines for the evaluation of results of

treatment of conductive hearing loss.

Secondary outcome

• Performance on pure-tone audiometry (mean air-bone gap, bone conduction thresholds, air conduction thresholds);

• Performance on speech audiometry;

• Disease-specific QoL and hearing benefit using the Glasgow Health Status Questionnaire and the Glasgow Benefit Inventory;

• General QoL using the Health Utilities Index 3 and EuroQol-5D;

• Tinnitus using the Tinnitus Handicap Inventory, Tinnitus Questionnaire and Utrecht Tinnitus Burden Questionnaire for severity of tinnitus;

• Vertigo using the Dizziness Handicap Inventory and Utrecht Vertigo Burden Questionnaire;

• Complication rate, including tinnitus, vertigo, sensorineural hearing loss, (immediate) dead ear and revision surgery.

Study description

Background summary

Rationale: 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.

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, general and disease-specific quality of life and complication rate.

Study design: double-blinded randomized controlled trial. Both patients and outcome assessors are blinded.

Study population: adult otosclerosis patients, aged 18 years and over, who are eligible for primary stapedotomy.

Intervention: primary stapedotomy, either with a 0.4 mm diameter piston or a 0.6 mm diameter piston.

Main study parameters/endpoints: primary outcome measure is postoperative air-bone gap closure on pure-tone audiometry at 12 months follow-up. 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).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 regard to hearing outcome.

Study objective

The use of a larger diameter piston in stapedotomy for otosclerosis is associated with superior hearing outcomes compared to the use of a smaller diameter piston, while maintaining equal rates of adverse events.

Study design

Follow-up directly postoperatively, at three months postoperatively and at one year postoperatively. Furthermore a monthly costs diary will be fulfilled.

Intervention

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

Contacts

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Eligibility criteria

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:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	13-03-2014
Enrollment:	140
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38574

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4369
NTR-old	NTR4509
CCMO	NL45622.041.13
OMON	NL-OMON38574

Study results