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

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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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28170

Bron
NTR

Verkorte titel
PISTON

Aandoening

Otosclerosis; stapedotomy; stapes surgery.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: University Medical Center Utrecht (UMCU)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	13-03-2014
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38574
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4369

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

Resultaten