A validation study of the translated Stapesplasty Outcome Test 25 for measurement of disease-specific quality of life in Dutch otosclerosis patients

Gepubliceerd: 04-03-2019 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24075

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Otosclerosis

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Validity of the translated SPOT-25

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction: otosclerosis is a common cause of acquired conductive hearing loss and can be treated using hearing aids or surgically in a procedure called stapedotomy. Surgical success rates or surgical results are usually reported using pure-tone audiometric thresholds and/or speech discrimination scores. Audiometric results and patient-reported quality of life after stapes surgery do not seem to correlate well. It is therefore our opinion that health-related quality of life measurements should be implemented as an additional outcome measure after stapes surgery. So far, there is a lack of a valid, reliable and clinically feasible measuring tool for determining health-related quality of life in Dutch patients with otosclerosis who undergo stapes surgery.

Methods and Analysis: a prospective validation study was designed to translate and validate the disease-specific Stapesplasty Outcome Test 25 (SPOT-25) in a population of Dutch otosclerosis patients who undergo stapes surgery. Seventy otosclerosis patients who will be undergoing primary stapes surgery and 50 healthy controls will be included. The otosclerosis patients will fulfill several questionnaires preoperatively, six to eight weeks postoperatively and eight to ten weeks postoperatively. The patients' audiometric results, which are measured routinely before and after undergoing stapes surgery, will also be used. The healthy controls will fulfill the translated SPOT-25 once. Firstly, the original SPOT-25 will be translated from German to Dutch in a six-step process. Secondly, the translated SPOT-25 will be pilot-tested in a subset of patients. Lastly, validity, reliability and responsiveness of the translated SPOT-25 will be analyzed.

Doel van het onderzoek

We expect the SPOT-25 to correlate with all three measurement instruments. We expect correlation between the change score in the "hearing function" domain of the translated SPOT-25 and the Glasgow Benefit Inventory to be higher than correlation between the translated SPOT-25 and Glasgow Health Status Questionnaire. We expect the "mental condition" and "social restrictions" domains to correlate better with the Glasgow Health Status Questionnaire than the Glasgow Benefit Inventory. Furthermore, we expect the "hearing function" domain of the SPOT-25 to correlate particularly well with mean gain in air-conduction thresholds, mean postoperative air-conduction thresholds and speech discrimination score, and less with mean gain in air-bone gap, postoperative mean air-bone gap and success defined as air-bone gap closure to 10 dB or less. We expect the other

domains to correlate poorly with audiometric results.

Onderzoeksopzet

Preoperatively, 6 to 8 weeks postoperatively and 8 to 10 weeks postoperatively in the otosclerosis patients. One measurement moment in the healthy controls.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria otosclerosis patients:
- Age ≥ 18;
- Otosclerosis based on a clinical history of progressive hearing loss and pure-tone audiometry showing a conductive hearing loss with an air-bone gap of 15 dB nHL or more in the range of 500, 1000, 2000 and 4000 Hz;
- Scheduled or on the waiting list for primary stapes surgery;
- Willingness and ability to fulfill the questionnaires outlined in the research protocol;
- Good understanding of the Dutch language.

Inclusion criteria healthy controls:
- Age between 30 and 60 years;
- Willingness and ability to fulfill the questionnaires outlined in the research protocol;
- Good understanding of the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria otosclerosis patients:
- Scheduled or on the waiting list for revision stapes surgery;
- Disability that could interfere with audiometric evaluation and/or questionnaire fulfillment.

Exclusion criteria healthy controls:
- A history of hearing loss, ear disease (with the exception of uncomplicated acute otitis or otitis media with effusion in childhood) or previous middle ear surgery (with the exception of the placement of ventilation tubes in childhood);
- Disability that could interfere with questionnaire fulfillment.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-11-2018
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7586
Ander register	METC UMCU : METC 18-768/C

Resultaten