Day-case stapes surgery compared to in-patient surgery in patients with otosclerosis.

Gepubliceerd: 21-08-2013 Laatst bijgewerkt: 15-05-2024

Day-case stapes surgery is associated with higher quality of life and higher cost-effectiveness, while maintaining equal hearing results, compared to in-patient stapes surgery.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29237

Bron
NTR

Aandoening

Otosclerosis (in Dutch: otosclerose).

Ondersteuning

Primaire sponsor: University Medical Centre Utrecht
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative air conduction on pure-tone audiometry at 12 months follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

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. Increasingly, stapes surgery is performed as a day-case procedure. The major drive toward day-case surgery has been financial, but most likely positively influences the patient's quality of life as a result of rapid discharge and rehabilitation. Even though stapes surgery seems well suited to a day-case approach, given the low complication rates and early recovery, evidence is scarce and of low quality.

Objective: to investigate the cost-effectiveness of day-case stapes surgery compared to in-patient stapes surgery and the effect of both methods on hearing outcomes, quality of life and complication rates (mainly tinnitus and vertigo).

Study design: un-blinded randomized controlled trial.

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

Intervention (if applicable): stapes surgery, either day-case or in-patient.

Main study parameters/endpoints: primary outcome measure is postoperative air conduction 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, complications (with specific attention for tinnitus and vertigo) and cost-effectiveness.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: complication known to arise following stapes surgery are tinnitus, vertigo, sensorineural hearing loss or dead ear, alterations in taste and facial nerve complaints. Compared to routine clinical practice, the study requires that half of the participants undergo day-case surgery instead of in-patient surgery. A risk of unforeseen (overnight) admittance following day-case surgery is present. The benefits of day-case surgery are early discharge and early social and emotional rehabilitation.

Doel van het onderzoek

Day-case stapes surgery is associated with higher quality of life and higher cost-effectiveness, while maintaining equal hearing results, compared to in-patient stapes surgery.

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

a day-case versus an inpatient approach to stapes surgery for otosclerosis. Day-case surgery involves same-day admittance and discharge, whereas inpatient surgery involves admission the day before surgery and discharge one day after surgery. Hearing outcomes, quality of life, complication rates and cost-effectiveness will be evaluated using pure-tone audiometry and questionnaires following both methods.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18;

• 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 and a perceptive hearing loss < 35 dB nHL in the range of 500, 1000, 2000 and 4000 Hz;

• Willingness and ability to participate in all scheduled procedures outlined in the research protocol;

• General health allowing general anesthesia in an out-patient setting;

• Quick access to communication and transportation in case of any complications;

• Good understanding of the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Previous middle ear surgery (other than previous stapes 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:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	112
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44763
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3848
NTR-old	NTR4133

Register	ID
CCMO	NL45219.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44763

Resultaten

Samenvatting resultaten
N/A