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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29237

Source
Nationaal Trial Register

Health condition

Otosclerosis (in Dutch: otosclerose).

Sponsors and support

Primary sponsor: University Medical Centre Utrecht
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

- Performance on speech audiometry;
- General and disease-specific quality of life
- Tinnitus;
- Vertigo;
- Use of escape medication;
- Intraoperative and postoperative complications;
- Cost-utility analysis.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	112
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44763
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3848
NTR-old	NTR4133
CCMO	NL45219.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44763

Study results

Summary results
N/A