Day-case versus in-patient stapes surgery for otosclerosis: a randomized controlled trial.

Published: 12-09-2013
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To investigate hearing improvement following day-case stapes surgery compared to in-patient stapes surgery and the effect of both methods on quality of life, cost-effectiveness and complication rates (mainly tinnitus and vertigo).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Middle ear disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON44763

Source
ToetsingOnline

Brief title
Day-case stapes surgery.

Condition

- Middle ear disorders (excl congenital)

Synonym
ossification, otosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Day-case, Otosclerosis, RCT, Stapes surgery

Outcome measures

Primary outcome

Primary outcome measure is postoperative air conduction on pure-tone audiometry

at 12 months follow-up.

Secondary outcome

Secondary outcome measures are hearing improvement on pure-tone and speech

audiometry, disease-specific and general quality of life, tinnitus, vertigo,

cost-effectiveness and complications.

Study description

Background summary

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.

Study objective

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

Study design

Un-blinded randomized controlled trial.

Intervention

Stapes surgery, either day-case or in-patient.

Study burden and risks

Complications 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

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

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 in the range of 500, 1,000, 2,000 and 4,000 Hz;
Willingness and ability to participate in all scheduled procedures outlined in the research protocol;
General health allowing general anesthesia;
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 stapes surgery;
Aberrant (middle ear) anatomy in one or both ears;
Co-morbid middle or inner ear pathology, osteogenesis imperfecta or an active ear infection in one or both ears;
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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2013
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-03-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-03-2018
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29237
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45219.041.13
OMON	NL-OMON29237