

# Comparison of stapes surgery with and without a vein graft in patients with otosclerosis: a randomised controlled trial

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To investigate which surgical technique (with or without vein graft interposition) is most (cost-)effective in patients with otosclerosis in terms of the average postoperative air-bone gap (ABG) closure, individual air and bone conduction thresholds...

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

## Summary

### ID

NL-OMON34834

### Source

ToetsingOnline

### Brief title

Stapes Surgery & Vein Graft in patients with otosclerosis

### 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:** Otosclerosis, RCT, Stapes Surgery, Vein Graft

## **Outcome measures**

### **Primary outcome**

The primary outcome will be postoperative hearing improvement in terms of the average ABG closure 12 months after surgery.

### **Secondary outcome**

- Postoperative average air-bone gap closure (dB), after 3 and 6 months.
  
- Bone conduction thresholds at 0.5, 1, 2, 3 and 4 kHz, after 3, 6 and 12 months.
- Air conduction thresholds at 0.5, 1, 2, 3 and 4 kHz, after 3, 6 and 12 months.
  
- Air bone gap at 0.5, 1, 2, 3 and 4 kHz, after 3, 6 and 12 months.
  
- Postoperative complications, after 3, 6 and 12 months:
  - Tinnitus
  - Vertigo
  - Dizziness
  - Postoperative sensorineural hearing loss (cochlear damage)
  - \*Dead ear\* (total deafness after surgery)
  
- Subjective patient\*s perception, after 3, 6 and 12 months.

- Quality of Life, after 3, 6 and 12 months.
- Spending/costs-log, after 3, 6 and 12 months.

## Study description

### Background summary

Otosclerosis is characterized by a deposit of new spongy bone around the stapes footplate, resulting in stapes fixation. The stapes is a vital link of the noise conduction system and fixation leads to hearing impairment. Replacement of the affected stapes with prosthesis is an effective method to achieve hearing improvement. Different surgical techniques are available. One technique applies a vein graft, harvested from the back of the patient's hand. The vein graft is placed beneath the prosthesis. Available literature suggests that a vein graft may increase postoperative hearing results, compared to prosthesis without vein graft. However, up to now no randomised controlled trials have been performed to compare both methods. Stapes surgery without vein graft is therefore still the standard technique in most otologic institutions.

### Study objective

To investigate which surgical technique (with or without vein graft interposition) is most (cost-)effective in patients with otosclerosis in terms of the average postoperative air-bone gap (ABG) closure, individual air and bone conduction thresholds, postoperative complications (tinnitus, vertigo, sensorineural hearing loss), postoperative subjective patient's perception and postoperative quality of life.

### Study design

A multicenter Randomised Controlled Trial including 180 patients with primary otosclerosis.

### Intervention

Stapes surgery, with and without a vein graft beneath the prosthesis.

### Study burden and risks

Both interventions carry the usual risks associated with surgery, i.e. pain, wound infection. Usual risks, associated with stapes surgery are tinnitus, vertigo, sensorineural hearing loss, taste complaints, a tympanic membrane

perforation and facial nerve complaints. In the vein graft group the anaesthetic period might be slightly longer due to vein graft harvesting from the back of the hand.

## Contacts

### Public

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### Scientific

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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  $\geq$  18 years
- Otosclerosis, diagnosed by an ear, nose and throat specialist in Utrecht or Hannover
- Primary otosclerosis
- Mean ABG  $>20$  dB based on the ABG values at 0.5, 1, 2, and 4 kHz
- Willingness and ability to participate in all scheduled procedures
- General health allowing general anaesthesia for the potential stapes surgery

## Exclusion criteria

- Age < 18 years
- Previous middle-ear surgery
- Co-morbidities: pregnancy, osteogenesis imperfecta, other middle- or inner-ear pathology (besides otosclerosis) In case of chronic/active ear infection in one or both ears; first treatment of this infection
- Abnormal anatomy in one or both ears
- Disability which could interfere with audiologic measurements or questionnaire fulfilment
- Inability or unwillingness to participate in the follow-up procedures

## Study design

### Design

Study phase:	2
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):	09-11-2010
Enrollment:	120
Type:	Actual

## Ethics review

Approved WMO	
Date:	02-09-2010
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL31170.041.10