

# Vestibular implantation and inner ear preservation

Published: 06-02-2018

Last updated: 15-05-2024

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Inner ear and VIIIth cranial nerve disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22960

### Source

NTR

### Brief title

Vestibular implantation and inner ear preservation

### Condition

- Inner ear and VIIIth cranial nerve disorders

### Health condition

bilateral vestibulopathy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academic hospital Maastricht (azM), The Netherlands

**Source(s) of monetary or material Support:** azM, Maastricht, The Netherlands, and MED-EL, Innsbruck Austria

## Intervention

- Other intervention

## Explanation

## Outcome measures

### Primary outcome

1. Assessment of preserved auditory function when the membranous labyrinth is kept intact.
2. Assessment of preserved auditory function after the membranous labyrinth is perforated with an electrode, which closes the opening directly.
3. Assessment of preserved auditory function after electrode manipulation.
4. Assessment of preserved auditory function after vestibular implantation, i.e. opening of the whole labyrinth and leakage of endolymph.

### Secondary outcome

5. Assessment of preserved vestibular function for different electrode positions with an electrode inside the semicircular canals.
6. Assessment of damage on tissue and cellular level with histopathological examination of labyrinths.

## Study description

### Background summary

Bilateral vestibular loss represents a major handicap with strong balance disturbances, higher risk of fall, visual symptoms (oscillopsia) and a loss of autonomy.

Prognosis is poor and treatment options are limited. At this moment, the department of ORL of Maastricht University Medical Center is working on a vestibular implant. Aim is to (partially) restore vestibular function.

However literature about hearing preservation during vestibular implantation is scarce. Until now, hearing preservation is only proven in a few animals. Humans who underwent implantation, were already deaf (our previous study) or lost hearing as a result of implantation (Washington group). The surgical technique and electrodes currently used, are not able to preserve hearing. Therefore surgical technique and electrode design must be

improved in order to be able to implant people with (sub)normal hearing. This study investigates an improved surgical technique, together with a new electrode design and histopathological examination of implanted inner ears, aimed at preservation of hearing and vestibular function.

## **Study design**

Ad 1. During surgery. After opening the bony semicircular canal (but leaving the membranous labyrinth inside the semicircular canal intact)

Ad 2. During surgery. After inserting an electrode inside the semicircular canal.

Ad 3. During surgery. After manipulation of the electrode inside the semicircular canal.

Ad 4. During surgery and after surgery. After opening the whole labyrinth with leakage of endolymph.

Ad 5. During surgery. After electrode placement (and before extensive electrode manipulation).

Ad 6. After surgery. Specimens of labyrinths are sent for histopathologic examination directly after surgery.

## **Intervention**

Routine labyrinthectomy with temporary electrode insertion

The surgeon will use the routine retro-auricular approach with mastoidectomy and exposition of the labyrinth, typical for destructive surgery of the labyrinth. Electrodes will be inserted into the labyrinth (specifically the semicircular canals) to evaluate insertion, manipulation and placement of the electrode design. Auditory function is evaluated through ABR and electrocochleography (ECoChG) at every step of the surgery. After electrode manipulation inside the canals, the electrodes will be activated. Vestibular function in response to electrical stimulation will be measured. Afterwards the electrodes are taken out again.

The recordings will add at most 30 minutes to the destructive surgery. After the recordings, the whole labyrinth will be destructed as planned according to the initial surgery. Typically, the labyrinths would be disposed as medical waste, but here they will be fixed with paraformaldehyde and sent for histopathological examination.

## **Contacts**

### **Public**

Department of Otorhinolaryngology, Maastricht University Medical Center

Joost Stultiens  
P. Debyelaan 25

Maastricht 6229 HX  
The Netherlands

**Scientific**

Department of Otorhinolaryngology, Maastricht University Medical Center

Joost Stultiens  
P. Debyelaan 25

Maastricht 6229 HX  
The Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Adults (18-64 years)

Elderly (65 years and older)

Elderly (65 years and older)

### Inclusion criteria

- Having a disease that requires destructive surgery of the labyrinth
- Having residual hearing that can be monitored using Auditory Brainstem Response (ABR)
- >18 years old
- Giving informed consent

### Exclusion criteria

- Mentally incapacitated patients
- Carrier of any other implanted electronic device (e.g. pace-maker)
- Having an enlarged vestibular aqueduct on routinely made preoperative CT-scan
- Not being able to obtain an ABR signal at the outpatient department

## Study design

### Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-12-2018
Enrollment:	10
Type:	Actual

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Approved WMO	
Date:	06-02-2018
Application type:	First submission
Review commission:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht
	Postbus 5800 6202 AZ Maastricht 043 387 6009 secretariaat.metc@mumc.nl

## Study registrations

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

ID: 55774

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL6839
NTR-old	NTR7017
CCMO	NL54761.068.15
OMON	NL-OMON55774

## Study results