Monitoring of auditory and vestibular function during destructive labyrinth surgery

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1. Monitoring of auditory function during destructive labyrinth surgery to study hearing preservation and vestibular implantation2. Monitoring of vestibular function during destructive labyrinth surgery to study better electrode position and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON55774

Source
ToetsingOnline

Brief title
Vestibular implantation and inner ear preservation

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
balance disorder, bilateral vestibular loss

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,MED-EL, Innsbruck, Oostenrijk.,MED-EL;Innsbruck;Oostenrijk.

Intervention

Keyword: bilateral vestibular loss, hearing preservation, vestibular implant, vestibular prosthesis

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

Secondary outcome

5. Assessment of preserved vestibular function with an electrode inside the

semicircular canals

6. Assessment of damage on tissue and cellular level with histopathological

examination of labyrinths after vestibular implantation

Study description

Background summary

Bilateral vestibular loss (BV) represents a major handicap with strong balance disturbances, higher risk of fall, visual symptoms (oscillopsia) and a loss of autonomy [1,2].
Prognosis is poor and treatment options are limited [3]. 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 [4,5,6].
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) [6] or lost

hearing as a result of implantation (Washington group). The surgical technique and electrodes currently used, are not able to preserve hearing [7,8,9]. 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.

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Study objective

1. Monitoring of auditory function during destructive labyrinth surgery to study hearing preservation and vestibular implantation
2. Monitoring of vestibular function during destructive labyrinth surgery to

study better electrode position and vestibular implantation
3. Histopathological examination of labyrinth to study damage on tissue and cellular level after vestibular implantation

Study design

Explorative Study

Study burden and risks

These patients are scheduled for destructive surgery of their labyrinth by opening their labyrinth completely. This means that they will undergo surgery that will (as a necessary side effect) cause hearing loss and loss of balance. During this surgery, their labyrinth is destructed in an abrupt way. This study will not destruct their labyrinth abruptly, but in steps: the labyrinth will not be opened completely, but first just three small portions of it. After the electrode insertion and measurements, the labyrinth will be destroyed completely. BERA-monitoring is a non-invasive way of measuring hearing thresholds and is routinely used in surgery. It adds no additional risks to the surgery. However, the patients will have to undergo a 30-minute BERA test at the outpatient department, in order to investigate whether a BERA signal can be obtained (if not, it can also not be obtained during surgery).
Electrocochleography is an investigation method that measures physiologic responses of the cochlea. It does not add any additional risks for the patient.
Video recordings will be made from the moment the mastoid is opened. This implies that only images of the mastoid will be recorded and therefore the patient cannot be recognized (e.g. de face of the patient is below the sterile sheets). This means that except time, the patients will not be exposed to any other risks than already was intended for the surgery.
When the canals are opened and inserted with the electrodes, waiting and measuring hearing after opening the labyrinth takes two minutes for each canal. Insertion of the electrode takes a couple of seconds, while monitoring hearing again will take two more minutes for each canal. Manipulation of electrodes takes approximately two minutes for all canals together. Measuring VECAP*s takes 15 minutes. VECAP*s are a safe way of stimulating the vestibular system, as has been shown in the protocol.
For short, surgery will take approximately 3x(2+2)+2+15=29 minutes longer than the normal procedure (as a reference: the initial surgical procedure takes more than three hours). Next to this, the patients have to come to the outpatient department to look whether a BERA-signal can be obtained (if not, it can also not be obtained during surgery).
The membranous labyrinth is taken out of the patient as part of the regular surgical procedure. For this study, the membranous labyrinth is anonymously used for histopathological examination instead of being thrown away as medical waste. Privacy of patients is therefore not compromised.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient has a disease that requires destructive surgery of the labyrinth
- Patient has residual hearing that can be monitored using BERA
- Patient is older than 18 years
- Patient gives informed consent

Exclusion criteria

- Patient is mentally incapacitated
- Patient is carrier of any other implanted electronic device (e.g. pace-maker)
- Patient has an enlarged vestibular aqueduct on routinely made preoperative

CT-scan

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Vestibular implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-10-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-12-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 22960
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54761.068.15
OMON	NL-OMON22960

Study results

Date completed: 05-07-2022

Actual enrolment: 22

Summary results
Trial is onging in other countries