Vestibulaire implantatie en binnenoorpreservatie

Gepubliceerd: 06-02-2018 Laatst bijgewerkt: 15-05-2024

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Binnenoor- en VIIIe hersenzenuwaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22960

Bron
NTR

Aandoening

- Binnenoor- en VIIIe hersenzenuwaandoeningen

Aandoening

bilateral vestibulopathy

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Academic hospital Maastricht (azM), The Netherlands
Overige ondersteuning: azM, Maastricht, The Netherlands, and MED-EL, Innsbruck Austria

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek

Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Anders

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-12-2018
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	06-02-2018
Soort:	Eerste indiening
Toetsingscommissie:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht Postbus 5800 6202 AZ Maastricht 043 387 6009 secretariaat.metc@mumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55774
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten