Hearing preservation in cochlear implantation surgery

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Combination of a round window insertion approach and a lateral wall electrode array minimizes insertion trauma

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20714

Bron
NTR

Verkorte titel
CIPRES

Aandoening

Sensorineural hearing loss, deafness

Ondersteuning

Primaire sponsor: Advanced Bionics
Overige ondersteuning: 3e geldstroom; Advanced Bionics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Hearing preservation; postoperative pure tone audiometry

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In order to preserve the residual hearing in patients with sensorineural hearing loss (SNHL) receiving a cochlear implant (CI), the insertion trauma to the delicate and microscopic structures of the cochlea needs to be minimized. The surgical procedure starts with the conventional mastoidectomy-posterior tympanotomy (MPT) approach to the middle ear, and is followed by accessing the cochlea, with either a cochleostomy (CO) or via the round window (RW). Both techniques have their benefits and disadvantages. Another aspect is the design of the electrode array. There are fundamentally two different designs: a ‘straight’ lateral wall lying electrode array (LW), or a ‘pre-curved’ perimodiolar cochlear lying electrode array (PM). Interestingly, until now, the best surgical approach and type of implant is unknown. Our hypothesis is that the combination of a RW approach and a LW lying electrode array minimizes insertion trauma, leading to better hearing outcome for SNHL patients.

Objective: Comparison of hearing preservation and outcome of two fundamentally different cochlear implants designs (LW or PM) and the two most used surgical approaches (RW or CO). Secondly, asses the structure preservation (i.e., scalar position) of each combination of electrode design/surgical approach. Thirdly, find objective electrophysiological measures for insertion trauma.

Study population: A total of 48 patients with severe SNHL, age ≥ 18 years, who meet the in/exclusion criteria used for cochlear implantation.

Study design: Randomized controlled single-blind trial consisting of four groups: I: RW and LW, II: RW and PM, III: CO and LW and IV: CO and PM.

Intervention: Randomization to one of the four groups.

Main study parameters/endpoints: Primary outcome: Pre- and postoperative hearing thresholds of (low frequency) pure tone audiometry (LF-PTA), secondary outcomes: scalar position of the electrode array, ECochG measures and speech perception score.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Cochlear implantation by way of a cochleostomy or round window approach, using different electrode array types, is the standard medical care for patients with severe bilateral hearing loss, as it is a relative simple and low-risk procedure that greatly benefits the patients. Cone-beam CT (CB-CT) imaging postoperatively leads to exposure of low-dose radiation (effective dose: 0.18 mSv), and is therefore considered to be of low-risk.

Doel van het onderzoek

Combination of a round window insertion approach and a lateral wall electrode array minimizes insertion trauma

Onderzoeksopzet

4-8 weeks, 3, 6 and 12 months after CI surgery

Onderzoeksproduct en/of interventie

Round window or cochleostomy insertion approach and either lateral wall or perimodiolar electrode array

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Dutch language proficiency
- 18 years or older
- Choice for Advanced Bionics implant
- Normal function of middle ear (i.e. no acute middle ear infections)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Prior otologic surgery in the implanted ear (excluding tympanostomy tube placement)

- Inner ear malformation present in the ear to be implanted (i.e. ossification, Mondini malformation)
- Retrocochlear pathology present in the auditory system to be implanted
- Neurocognitive disorders
- Sudden deafness

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	31-01-2020
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8586
Ander register	METC UMC Utrecht : METC 19-700

Resultaten