Hearing preservation in cochlear implantation surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20714

Source
Nationaal Trial Register

Brief title
CIPRES

Health condition

Sensorineural hearing loss, deafness

Sponsors and support

Primary sponsor: Advanced Bionics
Source(s) of monetary or material Support: 3e geldstroom; Advanced Bionics

Intervention

Outcome measures

Primary outcome

Hearing preservation; postoperative pure tone audiometry

Secondary outcome

scalar localization on computed tomography (i.e. scala tympani or vestibuli), speech

perception, ECochG intra- and postoperative,

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2020
Enrollment:	48
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-05-2020
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
NTR-new	NL8586
Other	METC UMC Utrecht : METC 19-700

Study results