

Hearing preservation in cochlear implantation surgery

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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, assess the structure preservation (i.e., scalar position) of each...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Hearing disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON49726

Source

ToetsingOnline

Brief title

Hearing preservation in cochlear implantation surgery

Condition

- Hearing disorders

Synonym

Deafness sensory neuronal hearing loss

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Advanced Bionics Corporation

Intervention

- Surgical procedure

Keyword: Cochlea, Deafness, Electrode array, Hearing preservation

Explanation

N.a.

Outcome measures

Primary outcome

Hearing preservation is the main outcome, which will be expressed in percentage. Hearing preservation is calculated by using the preoperative and postoperative puretoneaudiometry (PTA).

Secondary outcome

Scalar position of the electrode array (scala tympani or scala vestibuli assessed by CB-CT), ECoG (among others amplitude in μV) and eCAP (among others amplitude in μV) potentials, and speech perception test with/without noise in CVC words correct score (in percentage) with signal to noise ratio of 10 dB.

Study description

Background summary

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.

Study 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, assess the structure preservation (i.e., scalar position) of each combination of electrode design/surgical approach. Thirdly, find objective electrophysiological measures for insertion trauma.

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

Randomisation to one of the four groups.

Study burden and risks

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.

Contacts

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Trial sites

Trial sites in the Netherlands

Universitair Medisch Centrum Utrecht

Target size: 48

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Severe hearing loss, CI candidate
- 18 years of age or older
- normal function of middle ear (i.e. no acute middle ear infections)
- dutch language proficiency
- choice for Advanced Bionics implant

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 phase: N/A

Study type: Interventional research previously applied in human subjects

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment started
Start date (anticipated):	29-01-2020
Enrollment:	48
Duration:	14 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
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IPD sharing statement

Plan to share IPD: Undecided

Plan description

N.a.

Ethics review

Approved WMO	
Date:	14-01-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	11-12-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	16-05-2025
Application type:	Amendment

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
CCMO	NL71233.041.19
Research portal	NL-006726