Electrocochleography for Cochlear Implants: a postoperative study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56945

Source
ToetsingOnline

Brief title
Electrocochleography for Cochlear Implants

Condition

- Hearing disorders

Synonym
deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cochlear implants, Electrocochleography

Outcome measures

Primary outcome

The main study parameters will be the eCochG responses, more specifically, the amplitudes and the phase of the cochlear microphonic (CM) receptor potential, the summating potential (SP) and the compound action potential (CAP). In addition, the audiometric thresholds, electric field imaging, and insertion depth of electrode will be evaluated.

Secondary outcome

Clinically obtained CT-imaging scans to define the electrode location

Study description

Background summary

Cochlear Implant (CI) candidacy has broadened the past years due to the advancements in CI technology and performance. Nowadays, many CI candidates have useful low-frequency residual hearing in the to-be-implanted ear. Residual hearing can aid the patients* pitch perception and speech intelligibility, especially when electric and acoustic hearing are combined by electroacoustic stimulation [1]. Preserving low-frequency residual hearing during surgery is important for pitch perception and speech intelligibility. Electrocochleography has been introduced clinically as a tool to preserve residual hearing by minimizing the amount of cochlear trauma inflicted during implantation [2]. In addition, intracochlear electrocochleography has the potential to objectively measure residual hearing and tuning curves post-operatively. To this date, the relation between eCochG thresholds and hearing thresholds is subject of debate, and how different pathologies affect eCochG responses remains unknown. In the LUMC a model of intracochlear electrocochleography was developed [3]. In the current study, electrocochleography thresholds will be measured postoperatively on multiple frequencies and will be correlated to audiograms and simulations with different aetiologies, with the aim to improve interpretation of post-operatively obtained eCochG responses.

In an accompanying non-WMO study we will evaluate the effectiveness of the intra-operative tool by retrospectively comparing patients who are measured intra-operatively with patients who were previously implanted.

Study objective

The objective is to improve the understanding of intracochlear electrocochleography for objective measurement of residual hearing. ECochG responses obtained postoperatively in patients with different aetiologies will be evaluated in concordance with hearing tests and a computational model.

Study design

Observational and longitudinal study

Study burden and risks

At three different dates eCochG measurements will be done. The eCochG measurements can be done during visits that are part of the routine protocol of care after cochlear implantation and are expected to add 30 minutes to the visits. Postoperative audiometric testing and imaging is part of standard clinical routine. There are no plausible complications with either the ECochG measurements or the audiometric testing postoperatively. There will be no direct benefit for the patient. Ultimately, the project will improve the accuracy and interpretation of the ECochG responses, which will benefit all CI-users.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Subject meets the normal clinical candidacy criteria (functional speech perception scores below 80%) for cochlear implantation.
- Subjects are implanted with the Advanced Bionics cochlear implant system
- Subjects have 80 dB or better pure tone unaided audiometric thresholds at 125, 250 or 500 Hz in the (to-be) implanted ear.
- Subjects have agreed to participate in the study via written informed consent.
- Subjects should be able to understand the written informed consent form.
- Subjects are at least 18 years of age

Exclusion criteria

Disorders other than a hearing impairment that could affect the study results, such as psychiatric disorders or physical disorders that would limit their ability to undergo testing (e.g., movement disorders, blindness etc);

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2024
Enrollment:	45
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-08-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL84595.058.24