Evaluation of an integrated electrocochleography function for the monitoring of residual hearing

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational invasive

Summary

ID

NL-OMON46549

Source
ToetsingOnline

Brief title
iECoG

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,Advanced Bionics

Intervention

Keyword: electrocochleography, residual hearing, soft surgery

Outcome measures

Primary outcome

The main study parameters are ECoG recordings, and specifically their amplitudes that will be compared before, during and after surgery. These measures can be correlated to the standard subjective clinical measures (pure tone audiograms) after surgery.

Secondary outcome

Benchmark recordings of the ECoG during surgery using standard (high-quality) BERA equipment. Similarly, eCAP recordings will be benchmarked against the normal standard-of care eCAP recordings obtained via the implant electronics. eCAPs will be analyzed through standard methods, including amplitude-growth functions and threshold measurements.

Study description

Background summary

A cochlear implant (CI) is a neural prosthesis that can restore hearing function in the profoundly deaf. Preserving residual hearing in the implanted ear is desirable to maximize auditory functions. During surgery, the implant must be inserted carefully to spare the residual hearing. To this purpose, we propose to monitor the auditory response of the inner ear intraoperatively via electrocochleography (ECoG).

Study objective

This is an exploratory validation study in a small group of subjects receiving a CI to verify if ECoG measurements with AB*s novel ECoG system are useful as an intra-operative tool for soft surgical techniques to spare residual hearing.

This trial may serve as a startup study to establish a standard clinical practice during CI surgery.

Postoperative ECoG recordings and standard audiometric recordings will be obtained to assess the stability of residual hearing postoperatively to validate that intraoperative ECoG is a valid predictor of postoperative residual hearing function.

Secondarily, benchmark comparisons for ECoG and eCAP recordings can be performed between standard clinical equipment (BERA machine) and the AB device.

Study design

This is an unmasked, exploratory, descriptive-observational validation study with a longitudinal component in a relatively small group of subjects.

Study burden and risks

There is minimal burden and negligible risk to subjects. All subjects are adults and scheduled for standard CI implantation. The audiometry data collected is also largely standard clinical practice. The longitudinal ECoG recordings will be confined to during regular clinical visits and will add approximately 15 minutes to the normal visit. The risks of the ECoG recordings are negligible post-operatively. During surgery, the ECoG machine needs to be brought into the OR (but will be kept away from the patient, alongside the normal clinically used eCAP equipment). An additional electrode needs to be placed in vicinity of the inner ear, i.e., in the operating area. Intraoperatively, a mere ~15 minutes of recording will be added to a 4-hour surgery. The added risk is considered negligible. Importantly, extra care will be taken to spare residual hearing in the implanted ear, which can promote beneficial outcomes postoperatively in terms of residual hearing function for the individual patient.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eligible for cochlear implantation, with residual hearing in the implanted ear

Exclusion criteria

No residual hearing, co-morbidities

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Electrocochleography (ECoG) device using a cochlear implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-01-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-10-2019
Application type:	Amendment
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	NL63847.058.17

Study results

Date completed: 23-01-2023

Actual enrolment: 13

Summary results
Trial ended prematurely