# Intra-operative and post-operative electrophysiological assessment of neural health in cochlear implant users

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The aim of this study is to measure eCAPs intraoperatively (and perform electrocochleography [ECochG] in case of any residual hearing) and to estimate cochlear health in these patients by applying insights gained from our guinea pig experiments.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

# Summary

### ID

NL-OMON52337

**Source** ToetsingOnline

**Brief title** Neural health assessment in cochlear implantation

# Condition

• Inner ear and VIIIth cranial nerve disorders

**Synonym** Deafness, profound sensorineural hearing loss

# Research involving

Human

# **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** industrie,MED-EL GmbH, Innsbruck, Oostenrijk

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### Intervention

Keyword: auditory nerve, cochlear implant, electrophysiology, hearing loss

### **Outcome measures**

#### **Primary outcome**

Primary outcome measures: amplitudes and latencies of the electrically evoked compound action potential (eCAP); secondary outcome measures: amplitudes and latencies of electrocochleography.

#### Secondary outcome

In order to assess the clinical applicability/usefulness of the aforementioned

measurements, these experimental measurements will be compared to routinely

(clinically) obtained data such as etiology, degree, and duration of hearing

loss, and speech intelligibility scores.

# **Study description**

#### **Background summary**

In case of substantial to complete loss of cochlear hair cells, cochlear implants (CIs) can partially restore hearing. While most CI users benefit significantly, some hardly experience any improved functional hearing. It is largely unclear why such variability in hearing improvement exists among CI users, although factors such as age at implant, duration of deafness, etiology of deafness, and degree of hearing loss prior to implantation appear to be predictive of measurements of hearing performance with a CI. such as word recognition in noise. In particular, the chances of good CI performance tend to be higher for young people with a short duration of non-profound deafness. To some extent, this optimistic prognosis can be attributed to the plasticity of the central nervous system, but the state of the neural auditory periphery (also called "cochlear health") plays an important role as well. In an effort to find functional objective measures indicative of this cochlear health, we have conducted several studies in recent years focusing on measuring the compound action potential (eCAP) in guinea pigs. For example, we identified several eCAP measures that seem to change as the auditory nerve degenerates.

For example, with increasing inter-phase gap (IPG) in the biphasic stimulus current pulse, eCAP latency is unchanged in normal-hearing guinea pigs, but becomes longer in deaf animals (Ramekers et al., 2014, J Assoc Res Otolaryngol 15). Conversely, the overall excitability of the population ("level50%") increases in normal-hearing animals, but not in deaf animals, with greater IPG (Ramekers et al., 2014, J Assoc Res Otolaryngol 15).

#### **Study objective**

The aim of this study is to measure eCAPs intraoperatively (and perform electrocochleography [ECochG] in case of any residual hearing) and to estimate cochlear health in these patients by applying insights gained from our guinea pig experiments.

#### Study design

This study is observational. The treatment that the participating patients receive (cochlear implantation) is no different from those who choose not to participate. In addition, for the participating patients, measurements will be taken at two moments (once immediately after implantation intra-operatively, and once 3-6 months post-operatively), which have no influence on the treatment.

#### Study burden and risks

Only during the postoperative measurements (3-6 months after implantation) the patient may experience some discomfort, because the eCAP measurements require a relatively loud hearing sensation to be generated electrically. Additional burden comes from the time the patient spends participating in the post-operative measurements. If possible, the moment of these measurements will be scheduled simultaneously with other regular (clinical) appointments, so that the patient does not have to come to the UMC more often than necessary.

# Contacts

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adolescents (16-17 years) Adults (18-64 years) Elderly (65 years and older)

# **Inclusion criteria**

Age >= 16 years. Capable of providing informed consent. Dutch as native language. The chosen type of cochlear implant must be supported by the available test equipment.

### **Exclusion criteria**

Neurological or mental disorders. Use of anticonvulsant medication or psychotherapeutic drugs. No measurable eCAPs on any of the available electrodes.

# Study design

### Design

Study type:Observational non invasiveMasking:Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-12-2022
Enrollment:	33
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	23-06-2022
Application type:	First submission
Review commission:	METC NedMec

# **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 CCMO **ID** NL76131.041.21