Assessing the prognostic value of advanced electrophysiological measurements for performance with a cochlear implant.

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

Summary

ID

NL-OMON47100

Source
ToetsingOnline

Brief title
Electrophysiological assessment of auditory nerve degeneration.

Condition

- Hearing 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: een bedrijf: MED-EL,MED-EL

Intervention

Keyword: Auditory Nerve, Cochlear Implant, Degeneration, Evoked Potentials

Outcome measures

Primary outcome

The effect of varying stimulation parameters (IPG, PD, and IPI) on the characteristics of the nerve and brainstem response and the correlation of that effect with speech perception performance.

Secondary outcome

The correlation between speech perception and tone decay.

The correlation between nerve and brainstem responses and tone decay.

Study description

Background summary

Presently, cochlear implantation is the only successful treatment available for the deaf or profoundly hearing impaired. A persistent problem is the large variation in speech perception performance between patients after implantation. One of the explanations could be that the auditory nerve, consisting of spiral ganglion cells (SGCs), degenerates due to the duration of inactivity, as a result of which the implant cannot function as well. If we want to investigate this, we have to find a way to measure the viability of the auditory nerve. Neither histology nor imaging techniques are an option.

Recent research from our lab on implanted deafened guinea pigs showed a correlation between the number and size of the SGCs and the change in response of the auditory nerve to varying stimulation paradigms. We would like to translate these findings to a human CI population. If we can find a correlation between the response of the nerve and speech perception performance, we will have a prognostic factor with which the expectations of the patient can be managed. In addition, tone decay measurements might vary between CI patients with good or poor speech perception. A recent pilot study (13-648) showed this

possibility and we would like to investigate this further.

Study objective

The primary goal of this study is to evaluate the effect of varying stimulation parameters (inter-phase gap, phase duration, en inter-pulse interval) on the nerve and brainstem response and to correlate this to speech perception performance with the CI. The secondary goal is to determine if tone decay can differentiate between CI patients with good or poor speech perception.

Study design

This is a pilot study with a prospective cross-sectional design, performed at the UMC Utrecht.

Study burden and risks

The risk of the electrophysiological and tone decay measurements is considered to be neglegible. Current levels are not higher than the safety limits that are used daily in the clinic and not higher than the maximal comfortable listening levels of the subject. The expected burden due to participation for the subjects consists two sessions of around 3 hours (and two sessions of 10 minutes and half an hour for one of the groups). Physical discomfort is comparable to what CI patients endure during routine clinical checks. Subjects will not have a direct benefit of this study. The results of this study will contribute to managing the expectations of patients and ensure a more personal fitting of the implant.

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

• Age >= 18 years.
• Capable to provide informed consent.
• Dutch as native language.
• Suffering from bilateral deafness for which a cochlear implant (CI) is the best suitable treatment as decided by the CI-team of the UMC Utrecht.
• The chosen type of CI 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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2016
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	CIPT-system (Cochlear Implant Psychophysics Test-system)
Registration:	No

Ethics review

Approved WMO Date:	27-05-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-01-2019
Application type:	Amendment
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

ID: 24268
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51970.041.15
OMON	NL-OMON24268