Electrophysiological assessment of auditory nerve degeneration

No registrations found.

| Ethical review | Positive opinion |
|-----------------------|----------------------------|
| Status | Recruiting |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON24268

Source NTR

Brief title PrECISI

Health condition

Hearing loss

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU), Department of Otorhinolaryngology and Head & Neck Surgery **Source(s) of monetary or material Support:** MED-EL GmbH

Intervention

Outcome measures

Primary outcome

Correlation coefficients between speech perception performance and eCAP/eABR parameters

Secondary outcome

Study description

Background summary

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

Rationale: Presently, cochlear implantation is the only successful treatment available for the deaf (or profoundly hearing impaired). Hearing with a cochlear implant (CI) depends, among others, on the presence of a healthy and sufficiently large population of spiral ganglion cells (SGCs) in the implantee (Seyyedi et al., 2014). These cells form part of the auditory nerve (AN) (Ramekers et al., 2014) and function as the interface between CI and brain. What we aim at in this study is identifying electrophysiological techniques which can provide information about the condition of the AN in alive implantees, where histology is impossible and imaging techniques are not sophisticated enough to characterize such a small structure.

Recently Ramekers et al. (2014, 2015) in our lab correlated changes in electrically evoked compound action potential (eCAP) characteristics acquired with advanced stimulation paradigms to quantified histological measures of SGC degeneration in guinea pigs. They found significant correlations for several of the eCAP characteristics. Now, we want to translate these findings in experimental animals to humans. More specifically, we hypothesize that electrophysiological measures acquired by varying the stimulus attributes inter-phase gap (IPG), phase duration (PD) and inter-pulse interval (IPI) reflect the condition of the AN and could be correlated to higher order functions such as speech perception performance.

Therefore, in the current pilot study, we plan to evaluate the prognostic value of eCAPs in cochlear implantees in order to establish objective measures/predictors for CI performance. The electrically evoked auditory brainstem response (eABR), which provides similar information as the eCAP (Prado-Guitierrez et al., 2006), will also be recorded. For evaluation of the effect of varying the stimulus attributes mentioned above, we intend to perform peroperative eCAP measurements and postoperative eCAP and eABR measurements. Speech perception performance will then be correlated to the electrophysiological data.

Objective: The main objectives of this pilot study are assessment of the effect of varying stimulus attributes (IPG, PD and IPI) on eCAP and eABR characteristics and relating this effect to CI performance measured in speech perception.

Study design and population: This pilot study will include 6 deaf adults who will be implanted with a CI and 6 deaf adults who already are implanted with a CI. The participants that will be

implanted with a CI will be subjected to four sessions. Participants already implanted with a CI will be subjected to two sessions – not receiving the peroperative measurement or a separate speech in noise test. Intervention (if applicable): Not applicable

Main study parameters/endpoints:

- 1. The effect of varying IPG, PD and IPI on eCAP and eABR characteristics.
- 2. The correlation between speech perception scores and derived eCAP and eABR measures.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The study protocol does not carry any step which could potentially be harmful for participating subjects. The eCAP and eABR recordings and the threshold determination tests as well as the speech perception performance tests are considered non-risk investigations. The applied current levels are not higher than the security limits of conventional test equipment or than the most comfortable listening levels of the subject. Considering the burden: for postoperative recordings, participants are asked to attend measurement sessions which will be scheduled in consultation and, if possible, during scheduled visits.

Study objective

Speech perception after cochlear implantation is still largely variable among patients. Research suggests that degeneration of the auditory nerve hinders CI outcome and that evoked potential measurements are correlated to the state of the auditory nerve. Hence, evoked potential attributes could be correlated to CI outcome. Therefore, in search for such a possibly predictive factor for performance after implantation we plan to perform evoked potential and speech perception measurements in CI patients.

Study design

Date of surgery, 6-8 weeks post-implantation, >6 months post-implantation

Intervention

Electrophysiological recordings: Electrically evoked Compound Action Potential (eCAP) & Electrically evoked Auditory Brainstem Response (eABR)

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Age \geq 18 years.
- Capable to provide informed consent.
- Dutch as native language.

- Suffering from bilateral deafness for whom a 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 non invasive |
|---------------------|----------------------------|
| Intervention model: | Crossover |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-09-2015 |
| Enrollment: | 12 |
| Туре: | Anticipated |

Ethics review

| Positive opinion | |
|-------------------|------------------|
| Date: | 24-07-2015 |
| Application type: | First submission |

Study registrations

Followed up by the following (possibly more current) registration

ID: 47100 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| NTR-new | NL5179 |
| NTR-old | NTR5327 |
| ССМО | NL51970.041.15 |
| OMON | NL-OMON47100 |

Study results