The acoustic change complex in cochlear implant users

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Primary Objective: To assess the level of agreement between ACC variables (amplitude, latency) in CI users and the FDT perceived by the same CI users.Secondary Objectives: • To assess correlations between speech perception and ACC variables, and...

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

Summary

ID

NL-OMON44023

Source
ToetsingOnline

Brief title
The ACC in CI users

Condition

- Hearing disorders

Synonym
Deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: KNO
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acoustic change complex, Cochlear implant, Deafness, Frequency discrimination

Outcome measures

Primary outcome

The ACC parameters (amplitude and latency) evoked in response to different stimuli and the freqency discrimination ability, assessed with FDT, within subjects. The FDT will be expressed in % (ratio of frequency change and reference frequency).

Secondary outcome

The individual speech reception in noise threshold will be expressed in dB ratio.

Study description

Background summary

Cochlear implantation (CI) is the preferred treatment option for both adult and paediatric patients with profound sensorineural hearing loss. In the rehabilitation period after implantation, CI users develop the interpretation of CI induced activity as sounds. A large variability in auditory performance occurs in this first period, and a certain variability persists after several years of CI use. The available objective measurements assessing auditory performance in CI patients are limited. This study aims at an objective measurement possibly related to speech intelligibility. Intelligibility of speech, which is a complex sound consisting of various frequency and amplitude changes, is related to the ability to perceive these subtle changes in frequency and intensity. CI users may experience difficulties recognizing these subtle changes, in particular when they adapting to CI induced 'hearing'. An electrophysiological measurement, such as the acoustic change complex (ACC), recorded from the auditory cortex, might be an appropriate objective tool to test whether tone changes are perceived. To date, little is known about the relation between the ACC and the perception of small tone changes in CI users. In this study we aim to assess the level of agreement between ACC parameters and frequency discrimination ability, assessed with Frequency Discrimination

Tresholds (FDTs), in the same CI users. This level of agreement could increase with CI hearing experience, which could imply that the ACC has predictive value for an individual*s maximum expected auditory performance.

Study objective

Primary Objective:

To assess the level of agreement between ACC variables (amplitude, latency) in CI users and the FDT perceived by the same CI users.

Secondary Objectives:

• To assess correlations between speech perception and ACC variables, and between speech perception and FDT.
• To explore development of ACC and FDT with CI use.
• To compare ACC and FDT between short and long term CI users, and between unilateral deaf and bilateral deaf CI users.
• To compare ACC and FDT between the CI ear and the normal ear within unilateral deaf CI users.

Study design

This study concerns an explorative pilot study with adult CI users as subjects. The study will be performed at the department of Otorhinolaryngology in the University Medical Center Utrecht.

All participants will undergo a test session with frequency discrimination tests and a speech perception test. Two frequency discrimination tests are used, the electrophysiological ACC and the FDT test. In order to assess speech perception, the speech reception threshold (SRT) is measured with the Digits In Noise (DIN) test.
This study will include a total of 30 subjects, 18 CI users with long term experience and 12 with short term CI experience. The 18 long term CI users will undergo one test session, the 12 short term CI users are followed longitudinally during their rehabilitation period with repeated test sessions. After the first test session in their first month of CI use the test session will repeated 3 times; after 3, 6 and 12 months of CI hearing experience.
Both the 'long term experience' group and the 'short term experience' group are further divided in 2 subgroups: Bilateral deaf and unilateral CI users.
All frequency discrimination tests for the unilateral CI users will take more time because their normal hearing ear is tested in addition to their CI ear.
Only the subgroup of 6 unilateral deaf subjects with short term CI experience will undergo one additional baseline measurement prior to activation of their CI to assess frequency discrimination and speech perception of their normal hearing ear only.

Study burden and risks

The ACC recording and the just noticeable difference tests are considered as non-risk investigations.
The procedure of ACC recording is principally the same as the recording procedure for the clinically applied ABR, CAEP and EEG recordings.
The expected burden due to participation for all subjects consists of approximately 3 to 4.5 hours per session. The tests will be performed during one visit to the outpatient clinic. These sessions will be scheduled in consultation with the subject and if possible, during the subjects clinically scheduled visits to the department of Otorhinolaryngology, so that no additional visits to the outpatient clinic are necessary.
Subjects will not have a direct benefit of this study, but the results of this study will contribute to the scientific knowledge of how frequency and intensity changes in stimuli are perceived in the auditory cortex of CI users. Furthermore, this explorative study will gain knowledge on the level of agreement between the ACC and FDT in short and long term CI users, which can be used for future studies.

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 and < 65 years
- Written informed consent
- *Cochlear* CI users

Exclusion criteria

Neurological or mental disorders
Use of anticonvulsant medication or psychotherapeutic drugs

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	ACC/CAEP stimulation with DECOS patientinterface PI2496-R
Registration:	No

Ethics review

Approved WMO Date:	02-11-2016
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	ID
CCMO	NL55064.041.15

Study results

Results posted: 06-03-2023

First publication
01-01-1900

URL result
Type
ext
Naam
journals.lww.com
URL