Gap Detection with Cochlear Implants

Published: 18-06-2013
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To measure the gap detection threshold in CI users and (NH control subjects) considering the effect with speech-like stimuli using direct stimulation or CI device.

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

Summary

ID

NL-OMON37349

Source
ToetsingOnline

Brief title
GDCI

Condition

- Hearing disorders

Synonym
Deafness; Hearing impairment

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cochlear Implant, Gap detection, Interrupted Speech, Temporal Processing

Outcome measures

Primary outcome

The threshold duration for identification of the gaps.

Secondary outcome

Not applicable

Study description

Background summary

It is well known that the cochlear implant (CI) devices assist in hearing and understanding speech. This is a highly specialized research designed to study only one aspect of the CI processing: Gap detection. In this experiment we will test the gap detection ability of the CI users with the speech as stimulus and compare them with normal hearing (NH) as control. We try to find the temporal threshold of gap detection in CI users.
Gap detection is the ability of listeners to detect silent periods in a continuous auditory stimulus. It is a measure of auditory temporal acuity. It is an essential process for distinguishing speech sounds and identifying phonemes even in NH listeners. For CI users it is of even more paramount importance because they rely heavily on temporal cues for understanding of speech.
Relatively little is known about the temporal acuity and gap detection abilities of impaired hearing. Even lesser is known about gap detection abilities in a complex time-varying stimulus such as speech. A previous study (Bhargava and Ba*kent, 2011) has shown that CI users may have difficulty in detecting gaps in speech like stimuli. The question is, what causes this? This could be due to the limitations imposed either by cognitive processing in CI users or by various aspects of CI processing involved in CI devices. By bypassing the CI device processor we would be able to rule out the effect of CI processor and provide more controlled stimuli.

Study objective

To measure the gap detection threshold in CI users and (NH control subjects) considering the effect with speech-like stimuli using direct stimulation or CI device.

Study design

Psychophysical hearing tests, intraparticipant comparison

Intervention

Not applicable

Study burden and risks

There is a small risk of too loud and unpleasant sound. This risk is excluded through the proper setting of the implant device. Apart from this, the equipment has been tested rigorously in advance to avoid the risk.

Apart from this risk, there are no other known risks to human subjects participating in this study. The implant is not able to generate electric currents to be which are harmful to the ear or the auditory nerve. This also applies if the implant is "controlled" from a computer, such as in these experiments.

Nevertheless, there is an insurance which covers any damage when, unfortunately, something should go wrong during the study. Subjects are informed about the existence of this insurance.

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

CI users: AB CI device; post-lingually implanted, with a free-field phoneme score better than or equal to 50% at 65 dB SPL; At least one year experience of using the CI. ;NH subjects: Hearing loss should be less than 20 dB HL for 500, 1000, 2000, and 4000 Hz.;Bothl: Native speakers of Dutch, of age between 18 years to 90 years;

Exclusion criteria

Inability to cooperate, medical and technical complications and pre lingual deafness.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2013

Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL38315.042.11

Study results

Date completed:	01-04-2015
Actual enrolment:	30

Summary results
Trial is onging in other countries