# Assessing auditory nerve degeneration by electrical stimulation in deaf patients with a cochlear implant

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To measure detection thresholds, loudness, and melody perception in CI recipients in order to assess extent of nerve degeneration between good and poor performers with respect to speech perception.

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

## Summary

### ID

NL-OMON40195

**Source**
ToetsingOnline

**Brief title**
psychophysical assessment of auditory nerve degeneration

### Condition

- Hearing disorders

**Synonym**
deafness, profound hearing loss

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Cochlear Implant, Nerve degeneration

## Outcome measures

### Primary outcome

difference between CI recipients with high and poor performance, with respect to detection thresholds, tone-decay time, melody recognition scores, and pulse rate detection limits.

### Secondary outcome

• To determine the range of test outcomes and clinical applicability for the three developed tests.

• To determine if the outcome of the Melody test correlates to musical background.

# Study description

### Background summary

Profound sensorineural hearing loss, or deafness, is caused by loss of sensory hair cells in the cochlea. In many cases, it is treated by cochlear implantation. A cochlear implant (CI) bypasses the hair cells in the cochlea. Via electrical currents the implant stimulates the auditory nerve, which results in the perception of sound. The CI provides some degree of auditory perception, and in the most successful cases leads to virtually normal speech perception in low-noise acoustic conditions. However, there is a wide spread in performance among CI recipients, one contributing factor is auditory nerve degeneration. Common clinical tests do not provide an adequate measure of auditory nerve status. In order to assess nerve degeneration we developed three different psychophysical tests for CI recipients. These tests are used to determine detection thresholds, loudness adaptation and pitch perception. In this protocol we refer to them as T-Békésy test, tone-decay test, and Melody-test. It is hypothesized that nerve functionality tested in this way, provides measures that correlate to nerve degeneration. Such measures, acquired right after implantation, could be used for diagnosis, to improve the CI

fitting process (setting of the various apparatus parameters), and might lead to new processing strategies that make voices and music sound more natural to CI recipients.

### Study objective

To measure detection thresholds, loudness, and melody perception in CI recipients in order to assess extent of nerve degeneration between good and poor performers with respect to speech perception.

### Study design

This is an observational pilot study performed at the University Medical Center Utrecht.

### Study burden and risks

The T-Békésy test, tone-decay test and Melody test are considered as a negligible-risk investigation since the current levels applied are not higher than used in daily conditions of usage. The expected burden due to participation for all participants consists of two sessions of approximately 120 and 80 minutes, respectively. The physical discomfort is comparable to what CI recipients endure in the routine clinical fitting process. Subjects will not have a direct benefit of this study. The results of this study will contribute to knowledge of the clinical applicability of the developed tests for assessing nerve degeneration in deaf patients with a cochlear implant, and could possibly be linked to 'Assessment of the condition of the auditory nerve by diffusion tensor imaging: A pilot study' (METC 13/493).

## 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

Subjects eligible for participation in the study are adults with a CI.;In order to be eligible to participate in this study, a subject must meet all of the following criteria:
o Age >=18 years.
o Unilaterally implanted.
o Capable to provide an informed consent.
o The type of CI must be supported by the test equipment. Therefore only CI recipients with PULSARci100 or SONATAti100 implant, manufactured by MED-EL, can be included.
o More than half a year of CI experience (6 month post implantation).;Additional criterion for the high performance group:
o CVC scores with CI >70% measured at 65 dB SPL;Additional criterion for the low performance group:
o CVC scores with CI <50% measured at 65 dB SPL

## Exclusion criteria

• Neurological or mental disorders
• Use of anticonvulsant medication or psychotherapeutic drugs

# Study design

## Design

**Study type:** Observational invasive
Masking: Open (masking not used)

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| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-05-2014 |
| Enrollment: | 12 |
| Type: | Actual |

### Medical products/devices used

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

## Ethics review

Approved WMO

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| Date: | 25-03-2014 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

## 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 | NL46946.041.13 |