Tinnitus suppression with electrical stimulation using cochlear implants (CI).

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The main objective of the present study is to investigate the optimal stimulation pattern for tinnitus suppression in a structured way. Our study will focus on two parameters: stimulus level and anatomical stimulation site inside the cochlea.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON37530

Source
ToetsingOnline

Brief title
tinnitus suppression with electrical stimulation.

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
phantom sensation of sound, tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Med-El

Intervention

Keyword: CI, neurotology, Tinnitus

Outcome measures

Primary outcome

The study variable is the intensity of the experienced tinnitus. Because

tinnitus is a subjective phenomenon, its intensity is identified by means of

Visual Analogue Scales (VAS).

Secondary outcome

The stimulus intensity is also identified by means of VAS.

Study description

Background summary

Tinnitus is a symptom defined as a perceived sound in the absence of an external source. Its prevalence is reported to be about 10%-15% of the general population and currently there is no cure for tinnitus. Recent research showed that changes in neuronal activity might underlie tinnitus pathology. Several recent studies, which are in general case-reports, show that tinnitus complaints may be reduced by restoring peripheral auditory neural activity by means of intracochlear electrical stimulation. However, structured studies to improve knowledge of the optimal stimulus parameters are limited.

Study objective

The main objective of the present study is to investigate the optimal stimulation pattern for tinnitus suppression in a structured way. Our study will focus on two parameters: stimulus level and anatomical stimulation site inside the cochlea.

Study design

The study consists of two experiments. In each experiment one stimulation parameter will be investigated using a randomized (controlled) trial. Both experiments will be repeated with the same subject. So there will be two test

days per subject.

Intervention

Through adjustments in the standard CI settings, the effect of various stimulation patterns on tinnitus will be investigated. Subjects will be exposed to external sounds from a mp3-player, which the CI converts to a controlled electrical stimulation in the cochlea.

Study burden and risks

Prior to the study, participants are asked to fill out two questionnaires (THI and Tinnitus characteristics) as part of the selection. Furthermore they are asked to pitch match their tinnitus. During the study, several specific electrical stimulation patterns will be applied using the patients* CI, remaining well within its conventional, clinical safety limits. The study consists of several conditions which take 6 minutes each. During each condition the subjects are asked to fill out two VAS every 30 seconds. At the end of each condition the overall stimulus effectiveness will be ranked by means of VAS. The patient will thus need to invest a few hours (approximately four hours) of his time, which is weighted against possible scientific study outcome. After the study the settings will be set back to the settings they had before participation, or to any setting they wish, in cases of benefit from testconditions.
The clinical implications are clear. When using a CI to manage tinnitus, the clinical processor that is optimized for speech perception needs to be customized for optimal tinnitus suppression.

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 patients (implanted > 3/4 year ago)
- Tinnitus, that is:
o Subjective (idiopathic)
o localized ipsilateral to the CI
o at least mild, that is
- Visual Analogue Scale-score > 3
- Tinnitus Handicap Inventory- score > 16
o Stable tinnitus (stable > 1/2 year)
- Willingness to participate in this research (informed consent)

Exclusion criteria

-objective tinnitus
-age < 18 years old
-Ménière's disease
-active middle ear disease

Study design

Design

Study type: Interventional
Masking: Single blinded (masking used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2012
Enrollment:	11
Type:	Actual

Medical products/devices used

Generic name:	Cochlear Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-07-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 20130
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL38528.068.12
Other	TC = 3383
OMON	NL-OMON20130

Study results

Date completed:	25-02-2013
Actual enrolment:	11