

Tinnitus suppression with electrical stimulation using cochlear implants.

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Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20130

Source

Nationaal Trial Register

Health condition

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.

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)

Source(s) of monetary or material Support: investigator initiated

Intervention

Outcome measures

Primary outcome

The primary study variable is the intensity of the experienced tinnitus. Because tinnitus is a subjective phenomenon, its intensity is identified by means of VAS.

Secondary outcome

A secondary study endpoint of the present study is the experienced stimulus intensity, its intensity is identified by means of visual analogue scales (VAS).

Study description

Background summary

Rationale:

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.

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) cross-over trial.

Study population:

Ten patients wearing a CI will be asked to participate in this study. In- and exclusion criteria will be applied to include subjects suffering from tinnitus which is considered to arise from cochlear deafferentiation.

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.

Main study parameters/endpoints:

The main study parameters are the perceived loudness of the experienced tinnitus and of the stimulus at hand. Both will be identified by means of Visual Analogue Scales (VAS).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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. 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 test conditions. 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.

Study objective

Our study will focus on two parameters: Stimulus level and anatomical stimulation site inside the cochlea.

Based on scarce literature, it is hypothesized that subthreshold and thus inaudible current levels suppress tinnitus to a lesser extent than above-threshold stimulation. Furthermore, it is hypothesized that tinnitus suppression is optimal when applying (narrow band) pitch-matched electrical stimulation. This expectation is based on the assumption that tinnitus arises from a reduction in neural activity in specific, deafferented regions of the cochlea. Stimulation in these specific regions will probably restore neural activity and thus possibly reduce perceived tinnitus.

Study design

The tinnitus- and stimulus intensity will be scaled each 30 seconds interval during the (6 minutes of) stimulation.

Intervention

This study consists of two parts in which every part investigates a single research question. First the effect of electrical stimulation level (current level) on tinnitus intensity will be investigated. Therefore, we include CI patients. It is a randomized controlled cross-over study including different interventions (current levels). Subthreshold (T-level and thus audible) current levels will be tested. Furthermore, we use a "sham-stimulation" as control condition. This is possible since subthreshold stimulation is included. Hypothesis: subthreshold electrical stimulation suppresses tinnitus less, compared to above-threshold electrical stimulation. Furthermore, the second part of our study investigates the effect of different anatomical stimulation sites inside the cochlea. This is a randomized cross-over study. Hypothesis:

tinnitus suppression is optimal for (small band) pitch matched electrical stimulation (i.e. electrode responsible for tinnitus pitch). This hypothesis is based on the assumption that tinnitus arises from a reduced (or lost) neuronal activity in specific deafferented areas of the cochlea. Electrical stimulation of these specific areas can restore neuronal activity and possibly suppress tinnitus. Subjects will be included for both research parts. Stimulus duration of any condition will take six minutes and tinnitus loudness as well as stimulus loudness will be measured by means of Visual Analog Scale (VAS). A mp3-player connected to the CI will be used to generate a highly controlled electrical stimulation.

Contacts

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Eligibility criteria

Inclusion criteria

1. CI-patients (implanted > ¾ year ago);
2. Experiencing tinnitus which is:
 - A. Subjective (idiopathic);
 - B. Localized ipsilateral to the CI;
 - C. At least mild, that is:
 - i. Visual Analogue Scale-score > 3;
 - ii. Tinnitus Handicap Inventory-score > 16.
 - D. Stable tinnitus (stable > 1/2 year).
3. Willingness to participate in this research (informed consent).

Exclusion criteria

1. Objective tinnitus;
2. Ménière's disease;
3. Active middle ear disease;
4. Age < 18 years old.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion	
Date:	05-04-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37530

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3231
NTR-old	NTR3383
Other	NL38528.068.12 : 38528 ABR
CCMO	NL38528.068.12
OMON	NL-OMON37530

Study results

Summary results

Arts RA, George EL, Chenault MN, Stokroos RJ: Optimizing intracochlear electrical stimulation to suppress tinnitus. Ear Hear 2015; 36(1):125-35.