Audiometric evaluation of tinnitus inhibition by cochlear implant stimulation.

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To evaluate the efficacy of various masking strategies in cochlear implants as a treatment for tinnitus in patients with profound hearing loss.

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

Summary

ID

NL-OMON34080

Source
ToetsingOnline

Brief title
Tinnitus inhibition by cochlear implants.

Condition

- Inner ear and VIIIth cranial nerve disorders
- Structural brain disorders

Synonym
noise in the head, tinnitus

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 implants, Electric stimulation, Tinnitus

Outcome measures

Primary outcome

The main outcome measure is the tinnitus loudness scaling of the patients on a scale from 0 to 10 (with 0 being very weak and 10 being very strong tinnitus) before, during and after the stimuli.

Secondary outcome

Not applicable.

Study description

Background summary

Subjective tinnitus is the perception of sounds in the absence of a physical sound source. It can only be perceived by the patient himself. The prevalence of tinnitus is 4.4% -20% in the general population and 66-100% in the population of cochlear implant candidates. A key hypothesis in the pathogenesis of subjective tinnitus is that it arises as a response of the central auditory system to peripheral hearing loss. Peripheral hearing loss results in a decrease of afferent input to the brainstem. This may result in an increase of spontaneous neural activity at several levels in the auditory brainstem and cortex, which is believed to potentially cause tinnitus. Several authors described the positive effect of electrical stimulation of the ear on tinnitus, with success rates ranging from 4-87%.The first report of subjective tinnitus being suppressed by electric stimulation through a cochlear implant was in 1976. After that several researchers have confirmed these results, showing that suppression of tinnitus occurs in 40-86% of the cochlear implant recipients. The mechanism by which electrical stimulation reduces tinnitus is still unclear. Increase in neural activity (masking) seem to play an important part, but also some (central) nervous system effect seems to play a part in the influence of electric stimulation on tinnitus suppression. In this study we will investigate the influence of various kinds of electrical stimulation by cochlear implants on tinnitus. These experiments may identify stimulus strategies that are potentially successful as a treatment of chronic tinnitus.

Study objective

To evaluate the efficacy of various masking strategies in cochlear implants as a treatment for tinnitus in patients with profound hearing loss.

Study design

parametric exploratory study

Intervention

A listening experiment will be performed. It consists of several runs. In each run, the subject listens to a stimulus for a certain amount of time. He records the loudness of the stimulus and the loudness of the tinnitus on a scale from 0 to 10 (with 0 being very weak and 10 being very strong), once every 15 seconds. This recording starts 1 minute prior to the stimulus onset, and last until the tinnitus has come to its original loudness after the end of the stimulus. The electrical stimuli will differ in: pulse rate, stimulation electrode, amplitude, and duration.

Study burden and risks

It is expected that patients will not experience disadvantage of this experiment. The burden that is additional to standard care is the time and effort that patients have to put in this experiment. Patients have to come to the hospital for an additional visit. The listening experiment is done once in each patient and will take approximately 120 minutes, including frequent breaks.

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

Patients should have a cochlear implant because of hearing loss and besides that they should have chronic tinnitus, >3 months, perceived in the head, constant in presence when the cochlear implant is off.

Exclusion criteria

- An otological condition that needs intervention by an ENT-surgeon
- A psychiatric condition that needs intervention by a psychiatrist
- A non-cooperative patient

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-10-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2010
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	NL32003.042.10