Tinnitus suppression with electrical stimulation.

No registrations found.

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

Summary

ID

NL-OMON28937

Source
Nationaal Trial Register

Health condition

Tinnitus - oorsuizen

Sponsors and support

Primary sponsor: Maastricht University Medical Center +
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. The tinnitus intensity will be ranked on a Visual Analogue Scale (VAS).

Secondary outcome

1. Tinnitus Questionnaire;

2. Tinnitus Handicap Inventory;

3. Tinnitus Loudness Matching;

4. Residual Inhibition.

Study description

Background summary

Recruitment will be accomplished in The Netherlands.

Study objective

Tinnitus (Aurium) is a symptom characterized by the perception of sound or noise in the absence of any objective external physical source. This disorder affects millions of people worldwide; its precise pathophysiologic mechanism is unknown. It has yet remained refractory to current medical treatment. It is supposed that tinnitus might be suppressed by restoring peripheral auditory neural activity. In clinical practice, conventional hearing aids are often used for this purpose with only limited success. When using a cochlear implant (CI), prior studies show tinnitus suppression in 65%-93% of the cases . It is hypothesized that the suppressive effect of electrical stimulation by CI is due to restoring the code of silence in the cochlea and is also feasible with a simple stimulation pattern (i.e. without environmental sound perception). Moreover, it is hypothesized that this effect can be maintained over time.

Study design

At regular base after CI implantation for adjustments of CI-settings and during the study.

Intervention

Control intervention: Standard CI.

Intervention: Subject specific optimal simple electrical stimulation (i.e. electrical stimulation independent of environmental sounds).

During the crossover study both conditions are alternated in three months intervals.

Contacts

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Eligibility criteria

Inclusion criteria

1. Ipsilateral: Severely hearing-impaired;

2. Contralateral: Moderate to normal hearing;

3. Experiencing tinnitus which is:

A. Continuous;

B. Ipsilaterally localized;

C. Characterized as a pure tone;

D. Severe;

E. Stable;

F. No reported suppressive effect from hearing aids.

4. Willingness to participate in this research.

Exclusion criteria

1. Pulsatile tinnitus;

2. Ménière disease;

3. History of psychiatric or neurological disorders or depression;

4. Use of antidepressant medication;

5. Cochleovestibular neurovascular conflict;

6. Congenital malformalities in auditory system;

7. History of vestibular schwannoma;

8. Ossified cochlea;

9. Active middle ear disease;

10. Age < 18 years old.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2012
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	29-03-2012

Application type: First submission

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
NTR-new	NL3222
NTR-old	NTR3374
Other	NL38789.068.11 : 11-2-093 METC MUMC
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A