Phase Out as a treatment for Tinnitus

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23737

Source
Nationaal Trial Register

Brief title
N/A

Health condition

tinnitus, Phase Out, oorsuizen

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: University Medical Centre Groningen

Intervention

Outcome measures

Primary outcome

The major aim of this study is disappearance (report mark) of the tinnitus lasting many hours (time).

Secondary outcome

Besides the mojor aims, different questionnaires will be used to determine for which kind of tinnitus patients, this treatment is most effective (THI, TRQ, VE, HADS, SF-36, Eysenck, type

D personality, SSQ and TCSQ).

Study description

Background summary

Approximately 10-15% of the general population complains about tinnitus. In spite of the many investigations over the years, little is known about the pathophysiology and the treatment of tinnitus. The last decade different therapies have been developed. One of the new therapies is called ‘Phase Out’. This therapy is based on the physical mechanism of sound. In physics, sound is a wave and can shift in phase over 360 degrees. The hypothesis is that, shifting phase provides a better residual inhibition. Following the hypothesis there is an increased efficacy in comparison with placebo sound. This means that the intensity of tinnitus is decreased with the Phase Out treatment and effects will be sustained.
In this prospective, double blind, randomized placebo controlled crossover trail, Phase Out treatment will be compared to a treatment with placebo sound in 60 subjects. The effects will be measured by daily report marks and tinnitus and general questionnaires after a week of treatment.

Study objective

This study examines the effect of The Phase Out treatment on chronic, incurable tinnitus in adult subjects in comparison with placebo sound. The expectation of this study is that Phase Out treatment is effective for a longer duration and results in increased residual inhibition than placebo sound.

Intervention

A subject will receive Phase Out treatment for thirty minutes three times a week for one week and placebo sound treatment on the same regime during another. One month interval is in between these two sets of treatment. If a treatment is started, the subject fills in a report mark on the “tinnitus loudness” and “tinnitus annoyance” in the tinnitus diary every evening till three weeks after the treatment session. One week after each week of therapy a subject receives the evaluating questionnaires and will sent them back after filling in.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects > 18 years;
2. Unilateral or bilateral tinnitus;
3. Predominant tone tinnitus by history;
4. Tinnitus for minimum of 3 months;

Exclusion criteria

1. Acoustic neurinoma;
2. Aortic/ outflow tract stenosis;
3. Pulsatile tinnitus;
4. Pregnancy;
5. Inability to correct use of test equipment: unable to cooperate during audiologic examination;
6. Known tinnitus etiology, which would demand other treatment;
7. Hearing loss greater than 60 decibel compared with standardized normal hearing on standard frequencies of a tone audiogram (250; 500; 1000; 2000; 4000 en 8000 hertz).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007
Enrollment:	60
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL908
NTR-old	NTR932
Other	: N/A
ISRCTN	ISRCTN17631678

Study results

Summary results
N/A