Phase Out as a treatment for Tinnitus

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23737

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

tinnitus, Phase Out, oorsuizen

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: University Medical Centre Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2007
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL908
NTR-old	NTR932
Ander register	: N/A
ISRCTN	ISRCTN17631678

Resultaten

Samenvatting resultaten
N/A