

Phase out as a treatment for chronic untreatable tinnitus: a double blind crossover trial

Submission date 11/04/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/04/2008	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of Groningen on the 26th June 2007 (ref: METc2007/061).

Study design

Randomised, placebo controlled, crossover, double blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Tinnitus

Interventions

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 send them back after filling in.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Outcomes will be measured at weeks five and nine.

Secondary outcome measures

Besides the major aims, different questionnaires will be used to determine for which kind of tinnitus patients, this treatment is most effective:

1. Tinnitus Handicap Inventory (THI)
2. Tinnitus Reaction Questionnaire (TRQ)
3. Vital Exhaustion (VE) questionnaire
4. Hospital Anxiety and Depression Scale (HADS)
5. Short Form questionnaire (SF-36)
6. Eysenck Personality Questionnaire
7. Type D Personality Scale
8. Social Support Questionnaire (SSQ)
9. Tinnitus Coping Style Questionnaire (TCSQ)

Outcomes will be measured at weeks five and nine.

Overall study start date

01/05/2007

Completion date

01/05/2009

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

60

Key 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 standardised normal hearing on standard frequencies of a tone audiogram (250, 500, 1000, 2000, 4000 and 8000 hertz)

Date of first enrolment

01/05/2007

Date of final enrolment

01/05/2009

Locations**Countries of recruitment**

Netherlands

Study participating centre

Universitair Medisch Centrum Groningen

Groningen

Netherlands

9700 RB

Sponsor information**Organisation**

University Medical Centre Groningen (UMCG) (The Netherlands)

Sponsor details

Department of Ear, Nose and Throat Medicine

P.O. Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/english/azg/>

ROR

<https://ror.org/03cv38k47>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

University Medical Centre Groningen (UMCG) (The Netherlands)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration