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

Submission date 11/04/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/04/2007	**Overall study status** Completed	
Last Edited 29/04/2008	**Condition category** Ear, Nose and Throat	

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