Repetitive Transcranial Magnetic Stimulation (rTMS) treatment for chronic tinnitus.

No registrations found.

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

Summary

ID

NL-OMON20766

Source
NTR

Brief title
N/A

Health condition

chronic tinnitus

NL: chronische tinnitus, oorsuizen

Sponsors and support

Primary sponsor: Department of Otorhinolaryngology
University Medical Centre Utrecht
Source(s) of monetary or material Support: University Medical Centre Utrecht

Intervention

Outcome measures

Primary outcome

Tinnitus severity measured with the tinnitus questionnaire

Secondary outcome

- Tinnitus handicap inventory

- VAS on burden, loudness, pitch, presence, variability and specific problems in daily life

- Beck depression inventory

- State trait anxiety index

- tinnitus analysis (pitch, loudness, minimal masking level, residual inhibition)

Study description

Background summary

Tinnitus is a phantom auditory perception of meaningless sound, meaning that there is registration of sound in the absence of an external or internal acoustic stimulus. It is a common problem (prevalence 7-19%) which may interfere with the ability to lead a normal life. Unfortunately, it is a very difficult symptom to treat because there are hardly any therapeutic options for the cause of tinnitus. Most therapies focus on alleviating the condition rather than treating the cause. Tinnitus is thought to be generated in the brain, as a result of functional reorganization of auditory neural pathways and tonotopic maps in the central auditory system, following damage to the peripheral auditory system. Repetitive Transcranial magnetic stimulation (rTMS) is a therapy, based on this concept of reorganization in the auditory cortex. It uses a pulsed magnetic field to disrupt the neural circuit and to thereby (temporarily) excite or inhibit certain brain areas, leading to the suppression of tinnitus. With this study we intend to answer the question whether rTMS can be an effective treatment for tinnitus.

Study objective

rTMS suppresses neural circuits using a pulsed magnetic field which temporarily excites or inhibits a certain brain area. It is thought that tinnitus is generated in the brain as a result of functional reorganization of auditory neural pathways and tonotopic pathways, leading to a hyperactivity in the central auditory system, following damage to the peripheral auditory system. It is hypothesized that rTMS can supress this hyperactivity and thereby supress tinnitus.

Study design

last rTMS treatment, 1 week after treatment, 1, 3 and 6 months

(VAS's daily for the first three months and monthly for the second three months)

Intervention

rTMS: bilateral 1Hz, 110% MT, 2000 stimuli on five subsequent days.

Contacts

Public
University Medical Centre Utrecht Department of Otorhinolaryngology

C.E.L. Hoekstra
Post address: G05.127
Heidelberglaan 100

Utrecht 3584CX
The Netherlands
Scientific
University Medical Centre Utrecht Department of Otorhinolaryngology

C.E.L. Hoekstra
Post address: G05.127
Heidelberglaan 100

Utrecht 3584CX
The Netherlands

Eligibility criteria

Inclusion criteria

1. Chronic, non fluctuating, tinnitus, demonstrated by means of the Diagnostic Protocol Tinnitus UMCU, of at least two months duration.

2. Age >18 years

Exclusion criteria

1. Treatable cause of the tinnitus

2. Use of anticonvulsant medication or other psychotherapeutic drugs

3. History of epilepsy or family members with epilepsy

4. Presence of active migraine

5. Presence of psychiatric, severe internal or heart diseases or other neurologic diseases besides epilepsy

6. Metal objects in and around body that can not be removed

7. Pregnancy (will be tested on the first day of rTMS using a urine pregnancy test)

8. Alcohol or drug abuse

9. Prior treatment with TMS

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2008
Enrollment:	52
Type:	Actual

Ethics review

Positive opinion

Date:	23-04-2008

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	NL1247
NTR-old	NTR1293
Other	METC nummer UMC Utrecht : 07-286/O
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A