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Repetitive transcranial magnetic stimulation (rTMS) for the treatment of chronic tinnitus

Submission date	Recruitment status	[_] Prospectively registered
12/09/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2017	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
05/06_1

Study information

Scientific Title
Repetitive transcranial magnetic stimulation (rTMS) for the treatment of chronic tinnitus

Study objectives

Chronic tinnitus is a severe and disabling disease with so far no efficient treatment. Accumulating data point to the involvement of dysfunctional neuronal activity in the central nervous system as one possible underlying cause of chronic tinnitus. rTMS has been shown to be able to non-invasively modulate cortical activity and holds therapeutic potential in other treatment-resistant diseases such as major depression. Pilot studies revealed promising therapeutic potential of rTMS in the treatment of chronic tinnitus.

The primary objective of this trial is to evaluate the efficacy of real rTMS versus sham rTMS in the treatment of chronic tinnitus by means of change of tinnitus severity according to the tinnitus questionnaire of Goebel and Hiller (baseline versus day 12).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University of Regensburg, 24/10/2006

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled multi-center trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic tinnitus

Interventions
rTMS will be administered according to current safety guidelines. Figure-of-eight-coils will be used for real stimulation. Sham stimulation will be carried out by tilting the coil 45° away from the skull with one wing touching the skull. The stimulation parameters have been chosen according to successful pilot studies. Patients will be randomized to 2 parallel treatment groups:

Group A will receive real stimulation: 2 x 5 sessions, 1 Hz rTMS, stimulation intensity 110% related to the individual motor threshold, 2000 stimuli per session, coil position 10-20 guided over left primary auditory cortex.

Group B will receive sham stimulation by angulation of the magnetic coil 45° away from the skull with one wing touching the skull. Coil positioning and stimulation parameters as for group A.

Treatment will be conducted over a period of 2 weeks, at a frequency of 5 sessions/week.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Tinnitus severity, measured using the tinnitus questionnaire of Goebel and Hiller at baseline and day 12

Key secondary outcome(s)
Tinnitus severity, measured using the tinnitus questionnaire of Goebel and Hiller, Tinnitus Handicap Inventory (THI), Tinnitus Severity scale and Cinical Global Impression Scale during the follow-up period (screening, baseline, days 5, 67 and 181)

Further outcome measures:
1. Quality of life, measured by the 12-item Short Form health survey (SF-12) at baseline, days 5, 12, 18, 67 and 181
2. Depressive symptoms, measured by the Beck Depression Inventory (BDI) at baseline, days 5, 12, 18, 67 and 181
3. Psychometric parameters of tinnitus, assessed by audiological evaluation at screening and day 18
4. Structural neuroplastic adaptation processes, detected by voxel-based morphometry at baseline and day 12
5. Cortical excitability, assessed by paired-pulse TMS at baseline and day 12

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Male or female in- and out-patients, age 18-70
2. Diagnosis of chronic tinnitus
3. Patient has a score of greater than or equal to 38 on the Tinnitus Handicap Inventory
4. Tinnitus duration of more than 6 months
5. Age-adjusted normal sensorineuronal hearing determined by an audiogram within the last 4 weeks, i.e. no more than 5 dB below the 10% percentile (DIN EN ISO 7029) of the appropriate age and gender group in all measured standard frequencies. Furthermore, no conductive hearing loss of more than 15 dB in neither of the measured standard frequencies
6. Patient naïve to rTMS-treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Key exclusion criteria
1. Objective tinnitus
2. Other forms of tinnitus treatment at the same time
3. Clinically relevant psychiatric comorbidity as judged by an experienced psychiatrist
4. Concomitant treatment with psychotropic drugs
5. History of or evidence of significant brain malformation or neoplasm, head injury, cerebral vascular events, neurodegenerative disorder affecting the brain or prior brain surgery
6. Severe unstable somatic comorbidity
7. Cardiac pace makers, other electronic implants, intracranial metallic particles
8. History of seizures or epileptiform activity
9. Pregnancy and lactation
10. Women in child bearing age without contraception
11. Patients who cannot communicate reliably with the investigator or who are not likely to cope with the requirements of the trial
12. Patient unwilling or unable to give written informed consent
13. Participation in a clinical trial within the last 30 days before start of this clinical trial or similar participation in another clinical trial

Date of first enrolment
01/11/2007

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Germany

Study participating centre
University of Regensburg
Regensburg
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93053

Sponsor information

Organisation
University of Regensburg (Germany)

ROR
https://ror.org/01eezs655

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft within a clinical studies programme (ref: HA 3547/4-1)

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017		Yes	No
Protocol article	protocol	15/04/2008		Yes	No