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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

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

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## 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 measure
Tinnitus severity, measured using the tinnitus questionnaire of Goebel and Hiller at baseline and day 12

### Secondary outcome measures
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

### Overall study start date
01/11/2007

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
138

### 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)

**Sponsor details**
Universitaetstr. 84
Regensburg
Germany
D-93042

**Sponsor type**
University/education

**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, DFG

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Germany

# 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

## Study outputs

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