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# Priming stimulation as an enhancement of low-frequency repetitive Transcranial Magnetic Stimulation (rTMS) for the treatment of tinnitus

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| **Submission date**<br>14/08/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>23/08/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/12/2020 | **Condition category**<br>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**
01/194

## Study information

## Scientific Title
Priming stimulation as an enhancement of low-frequency repetitive Transcranial Magnetic Stimulation (rTMS) for the treatment of tinnitus

## Study objectives
Low-frequency rTMS has been investigated for the treatment of hyperexcitability disorders such as auditory hallucinations and tinnitus. Experimental data indicate that the depressant effect of low-frequency rTMS can be enhanced by high frequency priming stimulation. In the proposed study we investigate whether priming improves therapeutic efficacy of low-frequency rTMS in a clinical application.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of the University of Regensburg, University Clinic Regensburg (ref: 01/194). Approved on 19.12.2001 (amendment on 19.2.2007).

## Study design
Randomized, controlled, parallel-design study.

## 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
Chronic tinnitus

## Interventions
Experimental intervention: Low frequency rTMS over the left auditory cortex with priming stimulation: 6Hz (90% motor threshold, 960 stimuli) followed by low frequency rTMS (110% motor threshold, 1Hz, 1040 stimuli/day) 5 days a week for two weeks.
Control intervention: Standard protocol of low frequency rTMS (110% motor threshold, 1Hz, 2000 stimuli/day), 5 days a week for two weeks.

## Intervention Type
Other

## Phase
Not Specified

### Primary outcome measure
Change in tinnitus severity according to the Tinnitus Questionnaire of Goebel and Hiller (baseline vs day 12).

### Secondary outcome measures
Reduction of tinnitus severity as measured by the Tinnitus Questionnaire of Goebel and Hiller (TQ; THI) during the follow-up period (screening versus baseline versus days 18, 59, 90).

### Overall study start date
01/03/2003

### Completion date
31/07/2007

## Eligibility

### Key inclusion criteria
1. Female and male in- and outpatients
2. Age 18-70 years
3. Diagnosis of subjective chronic tinnitus
4. Duration of tinnitus more than 6 months

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
32

### Key exclusion criteria
1. Patients with conductive hearing loss of more than 15dB
2. Objective tinnitus
3. Treatable otologic disorder
4. Involvement in other treatments for tinnitus at the same time
5. Clinically relevant psychiatric comorbidity
6. Clinically relevant unstable internal or neurological comorbidity
7. History of or evidence of significant brain malformation or neoplasm, head injury
8. Cerebral vascular events
9. Neurodegenerative disorder affecting the brain or prior brain surgery;

10. Factors militating against the use of TMS (e.g. cardiac pace makers or other metal implants)
11. Pregnancy

**Date of first enrolment**
01/03/2003

**Date of final enrolment**
31/07/2007

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**Universitaetsstr.86**
Regensburg
Germany
93053

# Sponsor information

**Organisation**
Regensburg District Clinic (Bezirksklinikum Regensburg) (Germany)

**Sponsor details**
Universitaetsstr. 84
Regensburg
Germany
93053

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.bkr-regensburg.de/

**ROR**
https://ror.org/01eezs655

# Funder(s)

**Funder type**

Other

**Funder Name**
Tinnitus Research Initative (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? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2008 | 31/12/2020 | Yes | No |