

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

Submission date 14/08/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/12/2020	Condition category Ear, Nose and Throat	☐ Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

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)

ROR
<https://ror.org/01eezs655>

Funder(s)

Funder type
Other

Funder Name
Tinnitus Research Initiative (Germany)

Results and Publications

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