Experimental Tinnitus Treatment with Transcranial Magnetic Stimulation

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Study Protocol

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This study involved an experimental treatment protocol delivering repetitive transcranial magnetic stimulation daily as a potential treatment for tinnitus that did not respond to prior attempted therapies. This was an open label study and the primary outcome of interest was a self-report scale of clinical improvement. The protocol involved delivering MRI-guided repetitive TMS. Three treatment targets were assessed in the first session that included the primary auditory cortex, the dorsolateral prefrontal cortex, and the precuneus. TMS was delivered at 1 Hz and 10 Hz at each site and the participant selected the precuneus target as the one associated with the greatest change in tinnitus. As a result, we targeted with high frequency TMS delivered to the precuneus daily. There was no change in tinnitus symptoms after a week of treatment using this protocol. Because there was only a single participant involved in the experimental treatment the statistical analysis was limited to evaluating whether there was a change in the self-reported scale of tinnitus severity, which was not observed. No adverse effect were observed.

1. Consent patients that have been referred to the Noninvasive Brain Stimulation Clinic at the University of Iowa.
2. Patients will complete the following before any treatments occur: Tinnitus Intake Questionnaire, Tinnitus Functional Index, Tinnitus Questionnaires, Iowa Tinnitus Primary Function, Clinical Global Improvement Scale.
3. Patients may undergo audiological assessment if they have not already been tested prior to the study.
4. Patients will be required to obtain an MRI prior to treatment to aid in navigated stimulation unless there is have access to a previous clinical MRI for this purpose.
5. MRI images will be loaded into BrainSight or Localite, which are both frameless stereotactic systems for MRI-guided TMS localization. If no MRI is acquired, the subject's head will be transformed to MNI standard space within the software. MRI navigation allows us to place specific stimulation targets onto each subject's MRI. For this study, the investigators will be targeting left dorsolateral prefrontal cortex, auditory cortices, and auditory association cortices; all targets are placed anatomically by a neurologist. Infrared trackers on the subject's head and TMS coil allow for navigated stimulation of anatomical targets on the cortex with millimeter precision.
6. The motor threshold of the subject will be assessed, which is the intensity of TMS required to elicit motor evoked potentials from the hand 50% of the time.
7. Subjects will be fitted with an EEG cap to record neural activity before, during, and after the initial test session.
8. Single TMS pulses or brief trains of repetitive TMS lasting a few seconds will be administered at 80 - 120% of motor threshold to targeted regions of the cerebral cortex and cerebellum. A typical experiment will last 30 minutes to 2 hours. The patients are told they can stop the experiment at any time.
9. After each stimulation, patients will be asked to rate any changes in symptom severity and whether any side effects were experienced (Tinnitus Questionnaires, Clinical Global Improvement Scale).

10. After the treatment session, the TMS pulse locations will be related to changes in symptom severity as measured by self-report. If any stimulation treatments were successful in reducing symptom severity, a treatment plan for that target will be discussed and follow-up treatments may be scheduled.

11. Follow up treatments will vary between patients but will typically consist of daily treatments for up to 4 weeks or until treatment response is sustained. The patient can withdraw from follow treatments at any time. Patients will be asked to complete the following at these visits: Tinnitus Functional Index, Tinnitus Questionnaires, Iowa Tinnitus Primary Function, Clinical Global Improvement Scale.