Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The Efficacy of Infra-low-frequency Transcranial Magnetic Stimulation and Evaluation of TMS-evoked Potentials in Subjects with Chronic Tinnitus: A Double-blind, randomized, controlled trial

Protocol summary

Study aim

1-The Efficacy of low-frequency Transcranial Magnetic Stimulation in Subjects with Chronic Tinnitus 2-Evaluation of TMS-evoked Potential components in Subjects with Chronic Tinnitus Vs. Normal Subjects

Design

clinical trial with 40 participants (20 normal cases and 20 patients), randomized ,controlled, with parallel groups and double-blinded

Settings and conduct

After initial examinations in Rasoul Akram Hospital, selected patients will attend investigative-treatment Sessions of simultaneous TMS-EEG in National Brain Mapping Laboratory

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal hearing; Right Handed; Bilateral Tinnitus; Tinnitus Involvment more than 6 month; Informed Consent Retent; Tinnitus Loudness more than 6 dB SL; THI Score greater than 58; VAS Score greater than 4 of 7 Exclusion criteria: History of seizures or severe physical illness; Metal implants or cardiac pacemaker; Significantly increased intracranial pressure; History of craniocerebral surgery; Severe alcohol abuse; History of emotional disorder before the onset of illness

Intervention groups

2 groups comprised of subjects with tinnitus disorder and 2 groups comprised of healthy people with different target brain areas Left Temporoparietal / Left Dorsolateral Prefrontal cortex are present in this study. patients during 5 consecutive sessions and normal cases during only one session receive active and sham TMS at a rate of 0.5 HZ.

Main outcome variables

Difference in energy levels of EEG frequency bands (delta, theta, alpha, ...) before and after TMS in patients with tinnitus disorder and normal subjects; Comparison of tinnitus severity by Visual Analog Scale (VAS);Comparison of Tinnitus Questionnaire (TQ) score; Comparison of Tinnitus Handicap Inventory (THI) score; Evaluation of Amplitude, Latency and Area under the curve of TMS-Evoked Potential Components in patients and normal subjects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140616018118N3**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **prospective**

Last update: **2018-06-10, 1397/03/20**
Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66504294

Email address

mahmoudian.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

ENT and Head & Neck Research Center

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Infra-low-frequency Transcranial Magnetic Stimulation and Evaluation of TMS-evoked Potentials in Subjects with Chronic Tinnitus: A Double-blind, randomized, controlled trial

Public title
The Efficacy of Infra-low-frequency Transcranial Magnetic Stimulation and Evaluation of TMS-evoked Potentials in Subjects with Chronic Tinnitus: A Double-blind, randomized, controlled trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Normal hearing Right Handed Bilateral Tinnitus Tinnitus Involvment more than 6 month Informed Consent Tinnitus Loudness more than 6 dB SL THI Score greater than 58 VAS Score greater than 4 of 7
Exclusion criteria:
History of seizure, stroke, and severe physical illness Metal implants or cardiac pacemaker Significantly increased intracranial pressure History of craniocerebral surgery Pregnancy Severe alcohol abuse History of emotional disorder before the onset of illness Participation in other clinical trials
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **5**
A total of 20 participants with tinnitus, each will receive five treatment sessions (on five consecutive days in a week) of transcranial magnetic stimulation (TMS) and simultaneous recording of the electroencephalography (EEG), that will be evaluated for either therapeutic effectiveness and changes in TMS-Evoked Potential (TEP) components. Also, 20 normal participants (normal hearing and without any tinnitus in the ear or in the head of its owner, according to inclusion and exclusion criteria) will receive one treatment session as control group in accordance with the above description . In this study, a total of 120 treatment sessions will be performed for all participants in the study (20 patients and 20 healthy people).
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple-individual-statistical software
Blinding (investigator's opinion)
Double blinded
Blinding description
participants are not Informed which kind of treatment They Receive. Investigator and data analyzer don't know any information about recorded data.
Placebo
Used
Assignment
Parallel
Other design features
controlled randomized trial

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of medical science
Street address
Iran university of medical science, near to Milad tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-12-10, 1396/09/19
Ethics committee reference number
IR.IUMS.REC 1396.32322

Health conditions studied

1

Description of health condition studied
Tinnitus
ICD-10 code
H93.1
ICD-10 code description
H93.2, H93.3, H93.8, H93.9

Primary outcomes

1

Description
Mean energy level difference among EEG frequency bands (delta, theta, alpha, ...) before and after TMS (Transcranial Magnetic Stimulation) in tinnitus

participants and normal control group.

Timepoint

patients: 26 minutes of simultaneous TMS-EEG in first and last sessions normal subjects: one session of 26 minutes simultaneous TMS-EEG

Method of measurement

recording EEG with active multi electrodes

2

Description

Comparison of tinnitus severity before and after TMS

Timepoint

At the beginning and end of each session, also before and after active and sham magnetic stimulation

Method of measurement

Visual Analog Scale (VAS) for participants with tinnitus disorder

3

Description

Comparison of Tinnitus Questionnaire score

Timepoint

At the beginning of the first session and at the end of the last session

Method of measurement

Tinnitus Questionnaire (TQ) for participants with tinnitus disorder

4

Description

Comparison of Tinnitus Handicap Inventory (THI) score

Timepoint

At the beginning of the first session and at the end of the last session

Method of measurement

Tinnitus Handicap Inventory (THI) for participants with tinnitus disorder

5

Description

Evaluation of Amplitude, Latency, and Area under the curve of TMS-Evoked Potential Components in tinnitus participants and normal subjects.

Timepoint

simultaneous with Transcranial Magnetic Stimulation

Method of measurement

By means of EEG Signal recording

Secondary outcomes

empty

Intervention groups

1

Description

Patients group A: in the first and 5th sessions, 5 minutes of Sham Stimulation at a rate of 0.5 Hz, 2 minutes of merely EEG recording ,15 minutes of active TMS with a rate of 0.5 Hz and an intensity of 110% resting motor threshold will be applied respectively. During these two sessions ongoing EEG is being recorded and the coil is placed at Left TemporoParietal (LTP) region. In the second, third and fourth sessions 20 minutes of only active TMS at a rate of 0.5 Hz and an intensity of 110% resting motor threshold will be applied to LTP region.

Category

Treatment - Devices

2

Description

Patients Group B: for this group the treatment-investigative sessions will be the same as patients group A, with the difference that the stimulations are applied at the Left Dorsolateral Prefrontal Cortex (Left DLPFC).

Category

Treatment - Devices

3

Description

Normal group C: During one session, 5 minutes of Sham Stimulation at a rate of 0.5 Hz, 2 minutes of merely EEG recording ,15 minutes of active TMS with a rate of 0.5 Hz and an intensity of 110% resting motor threshold will be applied respectively. During the session ongoing EEG is being recorded and the coil is placed at Left TemporoParietal region.

Category

Other

4

Description

Normal group D: During one session each participant will receive interventions exactly the same as normal Group C with the difference that the stimulations are applied at Left Dorsolateral Prefrontal Cortex (Left DLPFC).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram Hospital, ENT and Head & Neck Research Center and Department

Full name of responsible person

DR. Saeid Mahmoodian

Street address

Hazrat Rasoul Hospital, Maziar Mansouri Street, Sattarkhan Ave.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
ENT and Head & Neck Research Center
Full name of responsible person
DR. Mohammad Farhadi
Street address
Hazrat Rasoul Akram Hospital-Sattarkhan
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Postal code
1445613131
Phone
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Email
info@ent-hns.org
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
ENT and Head & Neck Research Center
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
ENT and Head & Neck Research Center
Full name of responsible person
DR. Saeid Mahmoudian
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
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Position
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Person responsible for updating data

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mahmoudian.s@iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

TMS-EEG data in tinnitus and normal subjects

When the data will become available and for how long

About January 2020

To whom data/document is available

Professors and faculty members of universities

Under which criteria data/document could be used

Research

From where data/document is obtainable

DR. Ṡaeid Mahmoodian

What processes are involved for a request to access data/document

Contact with DR. Mahmoodian

Comments