Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of RTMS on tinnitus patients

Protocol summary

Study aim
Determining the efficacy of Repetitive Magnetic Brain Stimulation (RTMS) in tinnitus disorder

Design
The design of this research is a semi-experimental type of pre-test-post-test. Using the Tinnitus Questionnaire (THI), 30 patients were selected as the sample size using available sampling method using Cochran's formula.

Settings and conduct
It includes all people (both men and women) who came to Al-Zahra Hospital and Ayatollah Kashani Hospital (Isfahan) in 1402 with complaints of tinnitus. People are compared in the beginning and before the rtms method (pre-test) and then after the implementation of the RTMS method again and as a post-test, and the post-test will be performed for them. The instrument used is the tinnitus questionnaire (THI), which is implemented as a post-test and a pre-test. The method of semi-experimental work is of pre-test-post-test type. And the patients are in the process of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) A woman or man with tinnitus with an average age of 30 to 65 years 2) No simultaneous use of drug treatments 3) Not using other treatment methods, including surgery and medicine, in the last 6 months 4) Sound perception without any external physical stimulus Exclusion criteria 1) Having a middle ear infection 2) Tooth and sinus infection 3) Having a job and activity with noise pollution

Intervention groups
Patients treated with 10 sessions of RTMS (Repetitive Transcranial Magnetic Stimulation) with an English Magstim device with plating site in cases of bilateral tinnitus in the left temporal lobe and in cases of unilateral tinnitus in the opposite temporal lobe

Main outcome variables
tinnitus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240319061335N1**
Registration date: **2024-04-15, 1403/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-15, 1403/01/27**
Update count: **0**

Registration date
2024-04-15, 1403/01/27

Registrant information

Name
Toraj Khaledian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3522 8310

Email address
khaledian12@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-24, 1403/01/05

Expected recruitment end date
2024-05-25, 1403/03/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of RTMS on tinnitus patients

Public title
Investigating the effect of RTMS on tinnitus patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A woman or man with tinnitus with an average age of 30 to 65 years2)) No simultaneous use of drug treatments3) 4) 5) Using the Tinnitus Handicap Inventory questionnaire2 Not using other treatment methods, including surgery and medicine, in the last 6 months Absence of other effective diseases Sound perception without any external physical stimulus
Exclusion criteria:
Having a middle ear infection Having a job and activity with noise pollution Tooth and sinus infection
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
Hezargarib, University of Medical Sciences,Isfahan,Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2024-02-13, 1402/11/24
Ethics committee reference number
IR.MUI.MED.REC.1402.431

Health conditions studied

1

Description of health condition studied
tinnitus
ICD-10 code
H93.1
ICD-10 code description
Tinnitus

Primary outcomes

1

Description
tinnitus
Timepoint
tinnitus before the start of the intervention (first day); It is measured 20 days after the start of treatment and 50 days after the start of treatment in the follow-up phase.
Method of measurement
Tinnitus Handicap Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: RTMS (Repetitive Transcranial Magnetic Stimulation) is a non-invasive method in the treatment of tinnitus in such a way that by providing electromagnetic pulses through electrodes placed on the head, it can reduce the excitability of neurons and neurotransmitters related to tinnitus and as a result of reducing the intensity of tinnitus. This study has an experimental group and it is evaluated in the form of pre-test-post-test and does not have a control group. Intervention group: the sample size of 30 people is selected using the available sampling method. People are compared in the beginning and before the rtms method (pre-test) and then after the implementation of the RTMS method again and as a post-test, and the post-test will be performed for them. The instrument used is the Tinnitus Handicap Inventory (THI), which is administered as a post-test and a pre-test.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center

Kashani hospital - Isfahan University of Medical Sciences- Alzahra hospital - Isfahan University of

Full name of responsible person
Mehrdad Rogha

Street address
Hezar jarib, Isfahan University of Medical Sciences

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rogha@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
By the patient and resident (There is no cost at all)

Full name of responsible person
Mehrdad Rogha

Street address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
By the patient and resident (There is no cost at all)

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mehrdad Rogha

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is confidential and is possible only with the consent of the patient

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable