Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The Efficacy of Repetitive Transcranial Magnetic Stimulation in Patients with Major Depressive Disorder Resistant to First-line Pharmaceutical Therapy: A Double-blinded Randomized Clinical Trial

Protocol summary

Study aim

The Efficacy of Repetitive Transcranial Magnetic Stimulation in Patients with Major Depressive Disorder Resistant to First-line Pharmaceutical Therapy: A Double-blinded Randomized Clinical Trial

Design

In a clinical trial with the control group, double-blind, randomized phase 3 on 60 patients, to randomize patients, the block randomization method was used.

Settings and conduct

This study is a Double-blinded Randomized Clinical Trial that will be performed at 22 Bahman Hospital in Qazvin. Each patient will receive ten sessions of rTMS treatment. Each treatment session Will be applied at a frequency of 10 Hz for 5 seconds. The interval between the applied frequencies will be 10 seconds. In addition to active rTMS, sham rTMS will be used to prevent bias. All rTMS sham equipment was similar to the active rTMS group in that patients could hear the device's sound, but the magnetic current did not penetrate the brain.

Participants/Inclusion and exclusion criteria

En Inclusion criteria include the age of 18 to 70 years and a primary diagnosis of MDD by a psychiatrist based on the Diagnostic and Statistical Manual of Mental Disorders version V (DSM-V) criteria. Exclusion criteria include underlying diseases, history of rTMS treatment due to any disorder, history of seizures or neurosurgery, having a pacemaker, pregnancy, being diagnosed with a high risk of suicide, substance abuse, and unwillingness to participate in the study.

Intervention groups

Each patient will receive ten sessions of rTMS treatment. Each treatment session will receive a frequency of 10 Hz for 5 seconds.

Main outcome variables

change in depressive symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190612043877N1**
Registration date: **2022-06-13, 1401/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-13, 1401/03/23**
Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Alireza Hajseyedjavadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0621

Email address

dralihsj52@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-02, 1401/03/12

Expected recruitment end date

2022-07-03, 1401/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Efficacy of Repetitive Transcranial Magnetic Stimulation in Patients with Major Depressive Disorder Resistant to First-line Pharmaceutical Therapy: A Double-blinded Randomized Clinical Trial

Public title
The Efficacy of Magnetic Stimulation in Patients with Major Depressive Disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria were the age of 18 to 70 years Primary diagnosis of MDD by a psychiatrist based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders version V (DSM-V). the patients whose MDD was approved by a specialist according to MDD criteria and who had received and failed to respond to an episode of treatment (for at least six weeks) with effective tolerated doses of antidepressants were included in the study. The patients should have received the same medication from six weeks to the onset of the study and continued taking the drug during the study. Exclusion criteria comprised the presence of underlying diseases History of rTMS treatment due to any disorder History of seizures or neurosurgery, Having a pacemaker Pregnancy Being diagnosed with a high risk of suicide, substance abuse, and unwillingness to participate in the study.

Exclusion criteria:

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will assign patients to the intervention (active rTMS) and control (sham rTMS) groups. In this randomization method, the number of people assigned to each group is usually almost equal. The size of each block can be 5 to 10 people. In this way, for example, one type of rTMS is given to the first block, another to the second, and so on. Eligible patients will be allocated via concealed assignments using the sealed envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed double-blind and researchers and patients will be blind to this allocation. Depression assessors who review rTMS will also be blind to patient allocation. After completing the study and collecting the results, the relevant codes will be provided to each patient by a specialized team, and the implementation of the double-blind nature of the study was such that neither the participants nor the depression assessor is aware of the patient allocation.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Qazvin University of Medical Sciences

Street address
Shahid Bahonar Boulevard

City
Qazvin

Province
Qazvin

Postal code
34199-15315

Approval date
2022-05-30, 1401/03/09

Ethics committee reference number
IR.QUMS.REC.1401.039

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder Resistant to First-line Pharmaceutical Therapy

ICD-10 code
Major Depr

ICD-10 code description
F33

Primary outcomes

1

Description
depression symptoms

Timepoint
At baseline (before intervention) and the second and fourth weeks after intervention.

Method of measurement
The Hamilton Rating Scale

Secondary outcomes

1

Description
Severity of the disease
Timepoint
At baseline (before intervention) and the second and fourth weeks after intervention.
Method of measurement
Clinical Global Impression–Severity scale (CGI-S)

2

Description
Illness Perception
Timepoint
At baseline (before intervention) and the second and fourth weeks after intervention.
Method of measurement
the Brief Illness Perception Questionnaire (Brief IPQ)

Intervention groups

1

Description
• The rTMS protocol is performed by a MagVenture device (Denmark) with an 8-shaped coil equipped with a cooling system. Before each rTMS session, participants' motor threshold (MT) is determined by detecting the lowest stimulus energy level required to stimulate the motor cortex and producing five consecutive contractions of the right abductor pollicis brevis (APB) muscle. Stimulation is applied to the left DLPFC. The stimulation location in each participant is determined by moving the coil 5 cm anterior to the optimal surface location for activation of the right APB muscle. The experimental group will receive ten sessions of rTMS for two weeks, and the control group will receive sham rTMS for ten sessions. For more certainty, the positioning of the coil based on the stereotactic systems is also examined. 10 Hz frequency, 5 seconds stimulation, 10 seconds interruption, and 75 pulse trains is performed. 3750 pulses is applied in each session, and 37,500 pulses will be applied on the left during ten sessions. Stimulation is applied at 110% of the resting MT.
Category
Treatment - Devices

2

Description
Control group: Sham stimulation will be performed using an rTMS device with a sham coil, which is not creating any tactile sensation at the stimulation site and does not induce any cortical stimulation. The sham device provided a matching acoustic feel. Each participant receives ten rTMS sessions daily, regardless of the assigned group. Each treatment session will last 18 minutes. To eliminate external confounding effects and prevent bias, sham rTMS is delivered along with active rTMS using the same equipment so that patients can hear the device's voice. Still, no magnetic current will be discharged to the brain.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin University of Medical Sciences Bo Ali Hospital
Full name of responsible person
alireza haji seyed javadi
Street address
Railway Street
City
Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3355 5054
Email
ahsjavadi@qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyyed Mehdi Mirhashemi
Street address
Shahid Beheshti Blvd. - Movadat Sub-Department of Research and Technology, Qazvin University of Medical Sciences
City
QAZVIN
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 7006
Email
research.dpt@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
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
Qazvin University of Medical Sciences
Full name of responsible person
Alireza Haji Seyed Javadi
Position
Dean of the Medical School
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
خیابان راه آهن، بیمارستان ۲۲ بهمن
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3355 5054
Email
ahsjavadi@qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Alireza Haji Seyed Javadi
Position
The Dean of the School of Medicine
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Railway Street, 22 Bahman Hospital
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3355 5054
Email
ahsjavadi@qums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Alireza Haji Seyed Javadi
Position
The Dean of the School of Medicine
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Railway Street, 22 Bahman Hospital
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3355 5054
Email
ahsjavadi@qums.ac.ir

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
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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
After coding and unidentifiable, patients are shared based on the main consequences associated with the disease
When the data will become available and for how long
Start access valley one year after printing results
To whom data/document is available
Researchers at General Medical Universities
Under which criteria data/document could be used
For scientific exploitation
From where data/document is obtainable
Ali Akbar Shafikhani, Qazvin University of Medical Sciences, ali.shafikhani@yahoo.com
What processes are involved for a request to access data/document
Send an email explaining the reason for the request
Comments