

# 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

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

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Railway Street, 22 Bahman Hospital

**City**

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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**

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**Phone**

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**Email**

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**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**