

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

7 Effect of Repetitive Transcranial Magnetic Stimulation (rTMS) on depression severity, response inhibition, cognitive flexibility and visuo-spatial memory in patients with Depressive Disorder

Protocol summary

Study aim

investigating the effect of two types of repetitive transcranial magnetic stimulation protocols in the severity of depression, cognitive flexibility, response inhibition, and visual-spatial memory in patients with depressive disorder.

Design

A) Before presenting the independent variable, 55 patients will be selected in the available method. They will then be initially assessed by the Beck Scoring Index and the Wisconsin, Corsi, and Go-Nogo Cognitive Tasks. B) In the Independent variable implementation stage, the subject will receive 10 sessions of treatment during 2 weeks. Sham's group will receive only artificial stimuli.

Settings and conduct

This study will be performed at the Azarbaijan Shahid Madani University. The subjects will not be explained whether they will be in the stimulus or sham group, and the individuals and their type of stimulus will be defined with a specific code.

Participants/Inclusion and exclusion criteria

Being right-hand Having physical health No trauma or seizures in the individual or family Not having other psychological disorders No dependence on psychotropic substances Not being pregnant No metal, prosthesis, implant, or pacemaker

Intervention groups

The first group with unilateral stimulation of DLPFC in patients with depressive disorder The second group with bilateral stimulation of DLPFC in patients with depressive disorder The third group with sham stimulation in patients with depressive disorder

Main outcome variables

Reducing the severity of depression; Improving patients' cognitive functions (improving cognitive flexibility; improving visual-spatial memory; improving response inhibition)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210211050329N1**

Registration date: **2021-03-02, 1399/12/12**

Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**

Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Fatemeh Asgharian asl

Name of organization / entity

Azarbaijan Shahid Madani University

Country

Iran (Islamic Republic of)

Phone

+98 41 3145 2406

Email address

fatemeh.asgharian@azaruniv.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

7 Effect of Repetitive Transcranial Magnetic Stimulation (rTMS) on depression severity, response inhibition, cognitive flexibility and visuo-spatial memory in patients with Depressive Disorder

Public title

Effect of rTMS on Cognitive Function of Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being right-hand Age between 25-45 Having physical health

Exclusion criteria:

Being pregnant Having metal, prosthesis, implant or pacemaker Dependence on psychotropic substances History of Trauma or seizures in the individual or family Having other psychological disorders

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple Randomization unit: individual Randomization tool: In separate sheets, we will write the names of all the participants in the study and will put them in a container, and then randomly will pick the names and will add the first one to the list of the unilateral stimulation group, the second to the list of the bilateral stimulation group, and the third to the control group list. We will continue this until the last person.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not be explained whether they are in the intervention group or in the control group (blinding takes place), but due to the difference in stimulation areas in the two intervention groups, blinding between intervention groups is not possible for participants. Due to the difference in stimulation areas in the intervention groups and the difference in the stimulation angle in the control group and the intervention groups, blinding is impossible for the researcher. However, the data analyzer will be blind because he will receive only the list of data specified by a different code. And the person does not know which code is for which group—for example, the number 25 for a unilateral group. The number 35 will be assigned to the control group and the

number 15 to the bilateral group, which in data analysis, the analyst will not be aware of the allocation of these numbers to the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Abresan. Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.TBZMED.REC.1398.1248

Health conditions studied

1

Description of health condition studied

Depressive Disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description

Depression score in Beck questionnaire and clients' performance in cognitive functions of response inhibition, cognitive flexibility, and visual-spatial memory

Timepoint

Before the intervention and after two weeks

Method of measurement

By Beck Depression questionnaire and Clients' Performance in Cognitive Tasks of Go-Go, Corsi, and Wisconsin

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Stimulation will be performed by using a Magstim super-rapid magnetic stimulator (Wales, UK). The unilateral group will receive stimulation of Left DLPFC (20Hz, 5s in each train, 2100 pulses, and 85% of Motor Threshold) for 10 sessions during 2 weeks(5 sessions each week). The coil will be placed at a 45-degree angle on the patient's scalp.

Category

Treatment - Other

2

Description

Intervention group 2: Stimulation will be performed by using a Magstim super-rapid magnetic stimulator (Wales, UK). The bilateral group will receive stimulation of left DLPFC (20Hz, 5s in each train, 1400 pulses, and 85% of Motor Threshold), followed by Right DLPFC stimulation (1Hz, 10s in each train, 700 pulses, and 110% of Motor Threshold) for 10 sessions during 2 weeks(5 sessions each week). The coil will be placed at a 45-degree angle on the patient's scalp.

Category

Treatment - Other

3

Description

Control group: In the control group, we will perform artificial stimulation and for 10 sessions for 2 weeks(5 sessions each week), but the coil will be placed at a 90-degree angle on the patient's scalp. So they will not receive any stimulation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Azarbaijan Shahid Madani University

Full name of responsible person

Ladan Vaghef

Street address

Tabriz, East Azarbaijan Province 35 km. of. Maragheh Hwy

City

Tabriz

Province

East Azarbaijan

Postal code

5375171379

Phone

+98 41 3432 7500

Email

l.vaghef@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azarbaijan Shahid Madani University

Full name of responsible person

Ali Ajami

Street address

Tabriz, East Azarbaijan Province 35 km. of. Maragheh Hwy

City

Tabriz

Province

East Azarbaijan

Postal code

5375171379

Phone

+98 41 2432 7526

Email

research@azaruniv.ac.ir

Web page address

<http://research.azaruniv.ac.ir/Page/33/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D9%BE%DA%98%D9%88%D9%87%D8%B4-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%D9%8A.html>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Azarbaijan Shahid Madani University

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

Azarbaijan Shahid Madani University

Full name of responsible person

Fatemeh Asgharian Asl

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Tabriz. valiar

City

Tabriz

Province

East Azarbaijan

Postal code

5158944399

Phone

+98 910 402 0414

Email

fatemeh.asgharian@azaruni.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Azarbaijan Shahid Madani University

Full name of responsible person

Fatemeh Asgharian asl

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Valiasr, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5158944399

Phone

+98 41 3145 2406

Fax**Email**

fatemeh.asgharian@azaruniv.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Azarbaijan Shahid Madani University

Full name of responsible person

Fatemeh Asgharian asl

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Valiasr, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5158944399

Phone

+98 41 3145 2406

Fax**Email**

fatemeh.asgharian@azaruniv.ac.ir

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

There is no more information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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