

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Repetitive Transcranial Magnetic Stimulation approved by FDA (rTMS-FDA) versus Repetitive Transcranial Magnetic Stimulation with concentration on Mirror Neuron System (rTMS-MNS) on emotion and mood regulation in patients with major depressive disorder: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of rTMS-FDA versus rTMS-MNS on emotion and mood regulation in patients with major depressive disorder **Design:** a randomized clinical trial. **Setting and conduct:** The eligible patients with major depressive disorder who will refer to Farshchian Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** major depressive disorder; age of 18 to 65 years; receiving standard anti-depression drugs. **Exclusion criteria:** pregnancy; drug abuse during the last month; drug addiction during the last six months; neurologic disease or convulsion; having metal implant; using lorazepam, benzodiazepines, monoamine oxidase enzyme inhibitors or bupropion in the last month. **Intervention group:** Transcranial Magnetic Stimulation approved by FDA for 30 minutes 5 times a week for 2 consecutive weeks. **Control group:** Transcranial Magnetic Stimulation with concentration on Mirror Neuron System for 30 minutes 5 times a week for 2 consecutive weeks. **Primary outcome:** (a) assessing excitement regulation before and 2 and 4 weeks after intervention using excitement adequacy ranking scale; (b) assessing mood regulation before and 2 and 4 weeks after intervention using POMS criteria; (c) assessing social perception before and 2 and 4 weeks after intervention by reading mind in the eyes. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization. **Blinding:** Not blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610209014N123**

Registration date: **2016-10-29, 1395/08/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-29, 1395/08/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-01-30, 1395/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Repetitive Transcranial Magnetic Stimulation approved by FDA (rTMS-FDA) versus Repetitive Transcranial Magnetic Stimulation with concentration on Mirror Neuron System (rTMS-MNS) on emotion and mood regulation in patients with major depressive disorder: a randomized clinical trial

Public title

Effect of Repetitive Transcranial Magnetic Stimulation approved by FDA (rTMS-FDA) versus Repetitive Transcranial Magnetic Stimulation with concentration on Mirror Neuron System (rTMS-MNS) on emotion and mood regulation in patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: major depressive disorder; age of 18 to 65 years; receiving standard anti-depression drugs.
Exclusion criteria: pregnancy; drug abuse during the last month; drug addiction during the last six months; neurologic disease or convulsion; having metal implant; using lorazepam, benzodiazepines, monoamine oxidase enzyme inhibitors or bupropion in the last month.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-09-25, 1395/07/04

Ethics committee reference number

IR.UMSHA.REC.1395.294

Health conditions studied

1

Description of health condition studied

Major depression

ICD-10 code

F32.3

ICD-10 code description

Severe depressive episode with psychotic symptoms

Primary outcomes

1

Description

assessing excitement regulation

Timepoint

before and 2 and 4 weeks after intervention

Method of measurement

using excitement adequacy ranking scale

2

Description

assessing mood regulation

Timepoint

before and 2 and 4 weeks after intervention

Method of measurement

using POMS criteria

3

Description

assessing social perception

Timepoint

before and 2 and 4 weeks after intervention

Method of measurement

by reading mind in the eyes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transcranial Magnetic Stimulation approved by FDA for 30 minutes 5 times a week for 2 consecutive weeks.

Category

Treatment - Other

2

Description

Control group: Transcranial Magnetic Stimulation with concentration on Mirror Neuron System for 30 minutes 5 times a week for 2 consecutive weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Mojtaba Taiebi

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Farshchian Hospital

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Mojtaba Taiebi

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty