

# 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

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Iran (Islamic Republic of)

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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  
Fahmideh Ave

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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

**Full name of responsible person**

Mojtaba Taiebi

**Position**

Medical Student

**Other areas of specialty/work**

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**Web page address**

**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*