

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) add-on therapy to Standard treatment in Multiple sclerosis Patients with Depression Symptoms in Sina Farshchian Hospital in Hamadan city

Protocol summary

Study aim

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) add-on therapy to Standard treatment in Multiple sclerosis Patients with Depression Symptoms

Design

A controlled clinical trial with parallel groups, phase 2-3 randomized, on 40 patients with multiple sclerosis with depression. Random blocks were used for randomization

Settings and conduct

This study is performed in Farshchian Hospital in Hamadan. Due to the fact that patients do not know about the assignment of the group, so a one-way blind study is performed. Patients receive 10-minute direct-current electrical stimulation of the brain with a current of 2 mA, and in the control group receive 10 inactive 20-minute sessions with the same device.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in the study, Patient with multiple sclerosis of any type and with moderate and high depression, Not receive repeated trans cranial magnetic stimulation and electroconvulsive therapy in the past two month. Exclusion criteria: Having a shunt and any other metal object near the head Interferon consumption, Pregnant or lactating women, Patients at risk of suicide, Patients with other psychiatric disorders such as bipolar disorder

Intervention groups

20 patients with multiple sclerosis of any type and with moderate to high depression receive direct current electrical stimulation of the brain for 10 sessions of 20 minutes with a current of 2 mA and in the control group receive 10 sessions of inactive 20 minutes with the same device.

Main outcome variables

The score of Montgomery-Asberg Depression Inventory, severity of disability and cognitive function in the two

groups of intervention and control before the intervention and after the tenth session are compared.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N11**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **prospective**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 3428 9706

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) add-on therapy to Standard treatment in Multiple sclerosis Patients with Depression Symptoms in Sina Farshchian Hospital in Hamadan city

Public title

Transcranial Magnetic Stimulation (rTMS) add-on therapy to Standard treatment in Multiple sclerosis Patients with Depression Symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to participate in the study Patient with multiple sclerosis of any type and with moderate and high depression Not receive repeated transcranial magnetic stimulation and electroconvulsive therapy in the past two months

Exclusion criteria:

Having a shunt and any other metal object near the head Interferon consumption Pregnant or lactating women Patients at risk of suicide Patients with other psychiatric disorders such as bipolar disorder

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the intervention, patients do not know about the assignment of the group, so a one-way blind study is performed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-01-30, 1399/11/11

Ethics committee reference number

IR.UMSHA.REC.1399.925

Health conditions studied**1****Description of health condition studied**

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes**1****Description**

Depression rate

Timepoint

before and after 10 sessions of intervention

Method of measurement

Montgomery-Asberg Depression Rating Scale (MADRS)

2**Description**

Fatigue severity test

Timepoint

before and after 10 sessions of intervention

Method of measurement

Fatigue Severity Scale

3

Description

Expanded Disability Status Scale

Timepoint

before and after 10 sessions of intervention

Method of measurement

Expanded Disability Status Scale

4

Description

Cognitive Assessment

Timepoint

before and after 10 sessions of intervention

Method of measurement

Montreal Cognitive Assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 session of 20 minute of trans cranial direct current stimulation by 2 ma

Category

Treatment - Other

2

Description

Control group: 10 inactive session of 20 minutes by the same deviceCategoryOther

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Amir Keshavarzi

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Amir Keshavarzi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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 not a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available