Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Amir Keshavarzi
Position
Assistant Professor
Latest degree
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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