

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) add-on therapy to Standard treatment in Major Depressive Disorder Patients with sexual dysfunction 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 Major Depressive Disorder Patients with sexual dysfunction in Sina Farshchian Hospital in Hamadan city

Design

This is a single blind randomized clinical trial, in which 40 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

This study is performed in Farshchian Hospital in Hamadan. Patients with major depression and sexual dysfunction are included in the study. Patients are unaware of group assignment, so a single blinded 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: Consent to participate in the study; Patient with major depression (Montgomery-Asberg Depression Scale greater than 20); Not receive repeated transcranial magnetic stimulation and electro convulsive therapy in the past two months; Married men and women between 18 and 60 years old; Having sexual dysfunction
Exclusion criteria: Patients at risk of suicide; Patients with other psychiatric disorders such as bipolar disorder; psychosis;schizophrenia.

Intervention groups

20 patients with major depression and sexual dysfunction receive 10 sessions of 20 minutes with 2 mA direct current and 10 sessions of 20 minutes passive with the same device in the control group.

Main outcome variables

The score of Montogomerie-Asberg Depression Inventory,

Hamilton Depression Scale, sexual function and cognitive function are compared in the intervention and control groups before the intervention and after the tenth session.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N15**

Registration date: **2021-06-08, 1400/03/18**

Registration timing: **prospective**

Last update: **2021-06-08, 1400/03/18**

Update count: **0**

Registration date

2021-06-08, 1400/03/18

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

Email address

m.faryadras@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-16, 1400/12/25

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 Major Depressive Disorder Patients with sexual dysfunction in Sina Farshchian Hospital in Hamadan city

Public title

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) add-on therapy to Standard treatment in Major Depressive Disorder Patients with sexual dysfunction.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in the study. Patient with major depression (Montgomery-Asberg Depression Scale greater than 20) Not receive repeated transcranial magnetic stimulation and electroconvulsive therapy in the past two months Married men and women are sexually active and married between 18 and 60 years old Having sexual dysfunction

Exclusion criteria:

Patients at risk of suicide Patients with other psychiatric disorders such as bipolar disorder, psychosis, schizophrenia

Age

From **18 years** old to **60 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

For patient's in sham group, we used the same coil in active group but we placed it perpendicular to patient's scalp, therefore we were able to reproduce the somatic vibration sensation and acoustic artifact without stimulating motor cortex. As patients would receive intervention in separate appointments and there was no contact between patients, apart from the operator of rTMS. Therefore, the trial will be run as single blind.

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

2021-05-01, 1400/02/11

Ethics committee reference number

IR.UMSHA.REC.1400.100

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

Major depressive episode

ICD-10 code

F32

ICD-10 code description

Major depressive episode

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

Depression

Timepoint

Before and after 10 sessions of intervention.

Method of measurement

2

Description

Sexual function

Timepoint

Before and after 10 sessions of intervention.

Method of measurement

Female Sexual Function Questionnaire and Arizona
Sexual Experience Scale

Secondary outcomes

1

Description

Cognitive Assessment

Timepoint

Before and after 10 sessions of intervention.

Method of measurement

Montreal Cognitive Function Questionnaire

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 sessions of 20 minutes with the same
device that is inactive.

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 1828 5015

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code
6517838695
Phone
+98 81182851015
Email
drkeshavarzi@yahoo.com

Person responsible for scientific 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
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81182851015
Email
drkeshavarzi@yahoo.com

Person responsible for updating data

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
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81182851015
Email
drkeshavarzi@yahoo.com

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