Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 disorde; 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

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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
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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

Montgomery-Sberg Depression Scale and Hamilton Depression Inventory

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
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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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Position
Assistant Professor
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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