Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The study of effectiveness of repetitive transcranial magnetic stimulation (rTMS) on anhedonia, rumination with their related neural circuits in patients with major depression

Protocol summary

Study aim
The study of the effectiveness and repetitive transcranial magnetic stimulation (rTMS) on anhedonia, rumination and neural networks associated with each of them

Design
Clinical trials with control group with randomized double-blind parallel groups.

Settings and conduct
The study is conducted at Atieh Clinical Neuroscience Center. Participants receive treatment for 10 sessions after being assigned to the intervention group. Before starting the treatment, the participants perform the Snaith-Hamilton Pleasure Scale (SHAPS) Rumination Response scale (RRS) and the Hamilton Depression Rating Scale (HDRS) at baseline and during the tenth session for clinical evaluation. qEEG will be taken from the participants to check the anhedonia and ruminantion networks at baseline and treatment completion.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Outpatients male and female with the range of 18-70 years of age, The diagnosis of Major depressive disorder (MDD) according to Diagnostic and Statistical Manual of Mental Disorders (DSM-V), Having beck depression inventory (BDI)>14, Having stable symptoms as defined by not requiring a change in medication for at least 4 weeks, Completion of consent form,Being under supervision of a psychiatrist. exclusion criteria:The history of rTMS treatment for any reason, having cardiac pacemaker,The risk of seizure with any reasons, pregnancy,High risk of suicide,Intracranial implant and other ferromagnetic materials close to the head

Intervention groups
There are 2 intervention groups in this study. The first group rTMS and the second group received sham rTMS. In the control group, the stimulation parameters are similar to the actual TMS group, except that the coil angel is 90 ° and perpendicular to the head.

Main outcome variables
Anhedonia; Rumination,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100615004191N3**
Registration date: **2018-02-06, 1396/11/17**
Registration timing: **retrospective**

Last update: **2018-05-05, 1397/02/15**
Update count: **2**

Registration date
2018-02-06, 1396/11/17

Registrant information

Name
Reza Kazemi

Name of organization / entity
University of Tehran

Country
Iran (Islamic Republic of)

Phone
+98 21 8401 2128

Email address
rezakazemi@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-12-21, 1395/10/01

Expected recruitment end date
2017-06-10, 1396/03/20

Actual recruitment start date

2016-12-21, 1395/10/01

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

empty

Scientific title

The study of effectiveness of repetitive transcranial magnetic stimulation (rTMS) on anhedonia, rumination with their related neural circuits in patients with major depression

Public title

The study of effectiveness repetitive transcranial magnetic stimulation (rTMS) on anhedonia and rumination in patients with major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Outpatients male and female with the range of 18-70 years of age The diagnosis of Major depressive disorder according to DSM-V Having BDI>14 Having stable symptoms as defined by not requiring a change in medication for at least 4 weeks Completion of consent form Being under supervision of a psychiatrist

Exclusion criteria:

The history of rTMS treatment for any reason Cardiac pacemaker The risk of seizure with any reasons Pregnancy High risk of suicide Intracranial implant and other ferromagnetic materials close to the head co-morbidity with disorders in axis I and II

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software was used for random sequence generation. The random allocation process was carried out by a researcher blinded to the random sequence in order to avoid bias in this field. SNOSE technique was used to hide it.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and outcome evaluators are blinded to the study groups. The outcome evaluator performs the evaluation without knowing which intervention group the participant belongs to. According to the explanations stated in the informed consent, the participants are told that they are randomly assigned to the intervention groups and, if they are in the control group, after the completion of the test, they will undergo the same number of sessions considered for the other patients. In the control group, the participant will receive the sham TMS. That is, all the parameters are the same as the actual TMS group, except that coil angle is different. Therefore, the participants are blinded to the type of treatment they receive.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT03468686

Registration date

2018-02-06, 1396/11/17

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-01-22, 1396/11/02

Ethics committee reference number

IR.IUMS.REC.1396.0339

Health conditions studied

1

Description of health condition studied

major depression disorder

ICD-10 code

F33

ICD-10 code description

Major depressive disorder, recurrent

Primary outcomes

1

Description
Anhedonia
Timepoint
baseline, ten session
Method of measurement
Snaith-Hamilton Pleasure Scale (SHAPS)

2

Description
Rumination
Timepoint
baseline, ten session
Method of measurement
Ruminative Response Scale (RRS)

3

Description
Anhedonia network
Timepoint
baseline, ten session
Method of measurement
EEG

4

Description
default mode network
Timepoint
baseline, ten session
Method of measurement
EEG

Secondary outcomes

1

Description
Score of depression
Timepoint
baseline, ten session
Method of measurement
Hamilton Depression Rating Scale

2

Description
score of anxiety
Timepoint
baseline, ten session
Method of measurement
Hamilton Anxiety Rating Scale

Intervention groups

1

Description
Intervention group: Repetitive transcranial magnetic stimulation
Category
Treatment - Devices

2

Description
Control group: Sham repetitive transcranial magnetic stimulation
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Atieh Clinical Neuroscience Center
Full name of responsible person
Reza Kazemi
Street address
No 23,Vali-nezhad St, Above of vanak Sq
City
Tehran
Province
Tehran
Postal code
1969713663
Phone
+98 21 8401 2138
Fax
+98 21 8401 2101
Email
rezakazemi@ut.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Atieh Clinical Neuroscience Center
Full name of responsible person
Reza Rostami
Street address
No 23, Vali-nezhad St, Above of vanak Sq
City
Tehran
Province
Tehran
Postal code
1969713663
Phone
+98 21 8401 2138
Fax
+98 21 8401 2101
Email
rrostami@ut.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Atieh Clinical Neuroscience Center

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Atieh Clinical Neuroscience Center

Full name of responsible person
Reza Kazemi

Position
Vice president of research

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No 23, Vali-nezhad St, Above of vanak Sq

City
Tehran

Province
Tehran

Postal code
1969713663

Phone
+98 21 8401 2138

Fax
+98 21 8401 2101

Email
rezakazemi@ut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Atieh Clinical Neuroscience Center

Full name of responsible person
Reza Kazemi

Position
Vice president of research

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No 23, Vali-nezhad St, Above of vanak Sq

City
Tehran

Province
Tehran

Postal code
1969713663

Phone
+98 21 8401 2138

Fax
+98 21 8401 2101

Email
rezakazemi@ut.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Atieh Clinical Neuroscience Center

Full name of responsible person
Reza Kazemi

Position
Vice president of research

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No 23, Vali-nezhad St, Above of vanak Sq

City
Tehran

Province
Tehran

Postal code
1969713663

Phone
+98 21 8401 2138

Fax
+98 21 8401 2101

Email
rezakazemi@ut.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
The information on the main outcome of the study can be shared.

When the data will become available and for how long
Access time: one year after the release of the results

To whom data/document is available

The researchers working in the academic institutions

Under which criteria data/document could be used

The study data is available for writing meta-analysis.

From where data/document is obtainable

To receive the data, the principal researcher of the project must be contacted via email Reza Kazemi email:rezakazemi@ut.ac.ir

What processes are involved for a request to access data/document

After receiving the application for documentation, if the conditions are met, the documentation will be submitted to the applicant by the principal researcher within a week

Comments