

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Evaluation of effectiveness of accelerated repetitive transcranial magnetic stimulation (rTMS) in adolescent patients resistant to one course of medication with antidepressants

Protocol summary

Study aim

Evaluation of effectiveness of accelerated repetitive transcranial magnetic stimulation in patients resistant to one course of medication with antidepressants in adolescents

Design

After the clinical diagnosis of the psychiatrist, the patient is referred to the TMS unit for basic evaluation. This intervention does not include the control group. The sample size is 15.

Settings and conduct

The patient's treatment sessions (TMS intervention) will be implemented during 3 weeks, which includes 6 treatment sessions. In the first week, the patient visits the unit three times, in the second week twice, and in the third week once, and receives treatment three times a day. rTMS protocol: rTMS intervention consists of 120% movement threshold, with a frequency of 10 Hz for 2.4 seconds and a rest interval of 15 seconds. In each daily visit, the patient receives 10,500 pulses. (a total of 63,000 pulses during the sessions) At the end of the sixth session, the patient is evaluated after the intervention by repeating the Hamilton depression scale and CGI. The results of the two tests will be analyzed by analysis of variance.

Participants/Inclusion and exclusion criteria

No response to at least one trial of antidepressant with appropriate dose and duration (6w) moderate to severe depression which is described with scores higher than 17 in Hamilton Depression Rating Scale Informed Consent Right Handedness Age between 13 and 18

Intervention groups

rTMS protocol: rTMS intervention in the form of 120% of the movement threshold, with a frequency of 10 Hz for 2.4 seconds and a rest interval of 15 seconds. Treatment sessions last for three 30-minute sessions with a 15-minute interval between sessions. Session 1 and 2

contain 83 trains. and session 3 contains 84 trains.

Trains refer to inserting pulses with 10 Hz frequency and 2.4 seconds duration.

Main outcome variables

Score of Hamilton depression rating scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220130053873N2**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Mahtab Motamed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9151

Email address

motamed88@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of accelerated repetitive transcranial magnetic stimulation (rTMS) in adolescent patients resistant to one course of medication with antidepressants

Public title

Effectiveness of accelerated repetitive transcranial magnetic stimulation (rTMS) in resistant depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

No treatment response to one trial of efficient dose with efficient duration
Moderate and severe depression defined by Hamilton score under 17
Informed Consent
Right-handedness
Age above 13 and under 18

Exclusion criteria:

Suffering from major psychiatric disorders except simple phobia and nicotine dependency
History of seizure in person or family
Taking medications that lowers seizure threshold
Risk of Suicide attempts
Psychosis
any magnetic or metal agent in the head or cardiac pacemaker
Pregnancy
No prior response to ECT

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2024-01-03, 1402/10/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.544

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

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major Depressive Disorder

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

Score of Hamilton depression rating scale

Timepoint

Prior to the study and 3 weeks later

Method of measurement

Hamilton Depression Rating Scale

Secondary outcomes**1****Description**

Clinical Global Improvement

Timepoint

Prior to the study and 3 weeks later

Method of measurement

Clinical Global Impression questionnaire

Intervention groups**1****Description**

Intervention group: The treatment sessions (TMS intervention) of the patient will be implemented during 3 weeks, which includes 6 treatment sessions. In the first week, the patient visits the unit three times, in the second week twice, and in the third week once. He receives treatment three times a day. rTMS protocol: rTMS intervention in the form of 120% of the movement

threshold, with a frequency of 10 Hz for 2. 4 seconds and a rest interval of 15 seconds. Treatment sessions last for three 30-minute sessions with a 15-minute interval between sessions. The patient receives 10,500 pulses in each daily visit. (63000 pulses in total during the sessions). The motor cortex is determined by moving the active coil on the left hemisphere until finding the place that leads to the contraction of the left thumb muscle (abductor pollicis longus) and on the cap of The patient is marked. Threshold of active movement is the minimum intensity that leads to the contraction of the contracted muscle in at least half of ten times when performing magnetic movement. Then, the standard location of magnetic therapy stimulation - that is, the right dorsolateral prefrontal cortex - is determined by advancing the coil 5 cm from the point of the motor cortex towards the front.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Javad Alaghband-rad

Street address

South Kargar Ave

City

Tehran

Province

Tehran

Postal code

1337159140

Phone

+98 21 5541 2200

Email

jalaghbandrad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Javad Alaghband-rad

Street address

Qods st. Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 81631

Email

jalaghbandrad@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Javad Alaghband-rad

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh hospital. South kargar

City

Tehran

Province

Tehran

Postal code

1337159140

Phone

009855419151

Email

jalaghbandrad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Javad Alaghband-rad

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh hospital. South kargar

City
Tehran
Province
Tehran
Postal code
1337159140
Phone
009855419151
Email
jalaghbandrad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahtab Motamed
Position
Assistant Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
South Kargar
City
Tehran
Province
Tehran
Postal code
1337159140
Phone
+98 21 5541 9151
Fax
Email
motamed88@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after de-identification

When the data will become available and for how long

The data can be made available 6 months after the results are published

To whom data/document is available

Researchers in academic and scientific institutions can access the data

Under which criteria data/document could be used

Data can be used for systematic reviews and meta-analyses if needed. It is necessary to mention the names of the main researchers of this research.

From where data/document is obtainable

In case of data request, write to
jalaghbandrad@gmail.com.

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

After receiving the request and its review by the main researcher, the data will be sent to the applicant along with a letter of commitment stating that the data will not be published without the name of the main researcher within one month.

Comments