Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim

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

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 pne 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 18 and 60

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: **IRCT20220130053873N1**
Registration date: **2023-09-27, 1402/07/05**
Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**
Update count: **0**

Registration date

2023-09-27, 1402/07/05

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

2023-10-02, 1402/07/10

Expected recruitment end date

2024-02-29, 1402/12/10

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 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 treatmentt 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 18 and under 60
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 he head or cardiac pacemaker Pregnancy No prior response to ECT
Age
From **18 years** old to **60 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
2023-01-11, 1401/10/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.666

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

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 questoinnaire

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
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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
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
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Person responsible for updating data

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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 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