Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of the effect of repeated transcranial magnetic stimulation (rTMS) in reducing the percentage of suicidal ideation in depressed patients compared with the control group.

Protocol summary

Study aim

1.Determining the effectiveness of repetitive transcranial magnetic stimulation in reducing the severity of suicidal ideation in depressed patient in comparsion with control group2.Reducing Hospitalization density of patients3.Reducing hospitalization costs

Design

A controlled, double-blind, randomized controlled clinical trial on 40 hospitalized depressed patients with suicidal ideation who used random allocation law for randomization

Settings and conduct

The study was performed on 40 depressed patients admitted to Iran Psychiatric Hospital who have suicidal ideation. All patients receive antidepressant medication and are randomly divided into intervention and control groups to evaluate the effect of transcranial magnetic stimulation. Blinding is when patients and the main researcher do not know whether the magnetic stimulation is placebo or real.

Participants/Inclusion and exclusion criteria

Incusion criteria:patient with major depression/dysthymic/Double depression with suicidal ideation Exclusion criteria:Less than 18 years old/Metal objects in the skull/Pregnant woman/History of seizures/Addiction/Borderline Personality disorder/Dementia

Intervention groups

Among depressed patient with suicidal ideation,40 eligible individuals with suicidal ideation Were selected and randomly divided into twio group of 20, intervention and control.Transcranial magnetism is Examined in reducing suicidal ideation

Main outcome variables

Decrease in suicide score in Beck questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201026049155N1**
Registration date: **2021-04-25, 1400/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-25, 1400/02/05**
Update count: **0**

Registration date

2021-04-25, 1400/02/05

Registrant information

Name

MEHDI HOSEINI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8824

Email address

dr.hoselni7252@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of repeated transcranial magnetic stimulation (rTMS) in reducing the percentage of suicidal ideation in depressed patients compared with the control group.

Public title
Evaluation of the effect of repeated transcranial magnetic stimulation (RTMS) in reducing the percentage of suicidal ideation in depressed patients compared with the control group.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with major depression with suicidal ideation Dysthymic patients with suicidal ideation Patients with double depression with suicidal ideation

Exclusion criteria:
Metal objects in the skull Pregnant lady History of convulsions Received an electric shock in a recent month Psychotic depression Postpartum Depression Addiction Mentally retarded Borderline personality disorder Dementia Use of bupropion and methylphenidate

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **4**
Beck Depression and Suicide Questionnaire is completed once before the start of treatment and once after the end of the third session of treatment and once at the end of the sixth session and once a month after treatment.

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation rule. :Depending on the sample size and using the random allocation method, the letter A is written on 20 pieces of paper and the letter B is written on 20 pieces of paper and the papers are folded so that the letters A and B are not clear. The papers are poured into a container and mixed, and by referring to any depressed person with suicidal thoughts accidentally opens one of the folded papers. if A:as a real magnetic stimulation and if B: was a placebo for patients, finally out of a sample of 40 people, 20 would randomly receive real magnetic stimulation and 20 would receive a placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
On the day after hospitalization of a depressed patient with suicidal ideation in the hospital, Beck Depression and Suicide Questionnaires are completed by the researcher. The researcher does not know about the type of intervention that real rTms or placebo is performed. The patient is sent to the rTms room .In this case, one of the folded papers is opened randomly by the operator of the machine, and if it was A, 6 sessions of real magnetic stimulation, and if it was B, 6 sessions of placebo is done for patients. Patient selection is done randomly by the device operator. Patients and researchers do not know whether the magnetic stimulation is real or Placebo light is sent by the magnetic excitation operator, but the placement of the coil of the device is 90 degrees, which prevents the waves from reaching the skull. The only person who knows the real thing or placebo is the device operator who writes the letter A or B in the relevant form next to the patient's name. Similarly, for 40 patients, the patient's name A or B will be registered in the relevant form. Finally, the completed form is given to the third person who analyzes the information. The researcher also gives the results of the questionnaires to this person who analyzes And there is no interference in the questionnaires and statistical analysis. After the statistical analysis is done, the intervention results are notified. Therefore, neither the researcher nor the patient is aware of the actual or placebo treatment and the study is double blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran Psychiatric Hospital; Km 8 Lashgari Bivd

City
Tehran

Province
Tehran

Postal code
1398913151

Approval date
2019-12-29, 1398/10/08

Ethics committee reference number
IR.IUMS.FMD.REC.1398.435

Health conditions studied

1

Description of health condition studied

1. Patients with major depression with suicidal ideation ,, 2. Patients with dysthymia with suicidal ideation ,, 3. Patients with double depression with suicidal ideation

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms,

Primary outcomes

1

Description

Decrease in Suicidal Score in Beck questionnaire

Timepoint

Before the intervention and after the third and sixth sessions and one month after intervention

Method of measurement

Beck Suicide Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Depressed patients with suicidal ideation for 6 sessions are given as a placebo treatment of repeated transcranial magnetic stimulation with magstim device made in England.The statistical population of the study includes all depressed patients with suicidal ideation referred to Iran Psychiatric Hospital in Tehran in 2021. 40 eligible people will be selected according to the sampling method . 20patient randomized receive placebo and 20 patient real transcranial magnetic stimulation (rTMS).) . The duration of treatment will be 30 minutes and patients will receive 6 sessions of intervention. The method of work is as follows: At the beginning of admission to the ward or emergency department, the SCID questionnaire, Beck Suicide Thought Questionnaire and Beck Depression Inventory are completed.In addition to SSRI antidepressant drug therapy, patients are randomly selected for real rtms or placebo (forty patients, twenty placebo patients and twenty real rTMS patients) and rtms is started during the first week of hospitalization, which lasts for two consecutive days (morning, noon). Afternoon) real treatment or placebo rtms is doneAt the end of the first and second day, the Beck Suicide and Depression Inventory is completed again. Also, all patients are followed up one month after the start of treatment and the Beck Suicide and Depression Inventory is completed for them to determine the lasting effects of treatment.

Category

Treatment - Devices

2

Description

Intervention group: Depressed patients with suicidal ideation for 6 sessions are given as a real treatment of repeated transcranial magnetic stimulation with magstim device made in England.The statistical population of the study includes all depressed patients with suicidal ideation referred to Iran Psychiatric Hospital in Tehran in 2021. 40 eligible people will be selected according to the sampling method . 20patient randomized receive placebo and 20 patient real transcranial magnetic stimulation (rTMS).) . The duration of treatment will be 30 minutes and patients will receive 6 sessions of intervention. The method of work is as follows: At the beginning of admission to the ward or emergency department, the SCID questionnaire, Beck Suicide Thought Questionnaire and Beck Depression Inventory are completed.In addition to SSRI antidepressant drug therapy, patients are randomly selected for real rtms or placebo (forty patients, twenty placebo patients and twenty real rTMS patients) and rtms is started during the first week of hospitalization, which lasts for two consecutive days (morning, noon). Afternoon) real treatment or placebo rtms is doneAt the end of the first and second day, the Beck Suicide and Depression Inventory is completed again. Also, all patients are followed up one month after the start of treatment and the Beck Suicide and Depression Inventory is completed for them to determine the lasting effects of treatment.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran psychiatric Hospital

Full name of responsible person

seyed Mehdi Hosseini

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Iran Psychiatric Hospital.km8 Lashgari Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motovallian

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Email
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Grant name
Vice Chancellor for Research, Iran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research, Iran 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
Iran University of Medical Sciences

Full name of responsible person
Seyed Mehdi Hosseini

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

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Seyd Mehdi Hosseini

Position
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Latest degree
Medical doctor

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

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All HOPS data can be shared from unidentifiable individuals

When the data will become available and for how long

Access starts in july 2022

To whom data/document is available

There are no restrictions for applicants

Under which criteria data/document could be used

Any research to help patients with psychiatric disorders is allowed

From where data/document is obtainable

Iran,Tehran,8 km of Shahid Lashgari Highway, Iran Psychiatric Hospital, Dr. Seyed Mehdi Hosseini Contact number 00989125955223

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

Correspondence or face-to-face referral to Iran Psychiatric Hospital, telephone or correspondence to e-mail address

Comments

Thank you for your patience and I wish you the best days with health