

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of Treatment with Repetitive Transcranial Magnetic Stimulation Combined with Drug Therapy with Drug Therapy Alone in Post-Traumatic Stress Disorder

Protocol summary

Study aim

Comparison of treatment with Repetitive Transcranial Magnetic Stimulation combined with drug therapy with drug therapy alone in PTSD

Design

The study is a three-blind clinical trial on all patients with PTSD. First, patients complete the Beck Depression Inventory and patients with a score of 17 or lower are included in the study. 30 patients are selected and placed in one of two groups A or B. Group A receives 1 Hz for 20 minutes at a time of 3 weeks and 5 times a week while continuing the drug treatment, and group B patients receive drug treatment and SHAM. At the end of each week, patients fill out the questionnaire again. At the end of the study, the mean scores of the questionnaire in both groups are compared to the beginning of the study and the other group to determine the effectiveness of each treatment regimen independently and in comparison with others, as well as the rate of remission.

Settings and conduct

By multi-stage random sampling, easy random sampling among patients with moderate to severe PTSD referred to the psychiatric clinic of 22 Bahman Hospital in Qazvin

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 60 years old, history of moderate to severe PTSD according to Beck Depression Inventory that do not score above seventeen, Exclusion criteria: having other psychiatric illnesses, history of seizures, history of Drug Abuse, history of neurosurgery complications, having implants

Intervention groups

Group "A" is the intervention group that is treated with rTMS device for 5 days a week (a total of 1,200 pulses / day) for 3 weeks at the same time as taking the drug. While patients in group "B" or the control group are only treated with standard drug regimen and sham is used for

them so that the device was placed on their scalp without magnetic stimulation.

Main outcome variables

Severity of post-traumatic stress disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171205037768N2**

Registration date: **2021-01-16, 1399/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-16, 1399/10/27**

Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

Mohsen Zamir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3355 5054

Email address

mzamir@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

2020-08-06, 1399/05/16
Actual recruitment end date
2021-02-23, 1399/12/05
Trial completion date
2021-02-23, 1399/12/05

Scientific title

Comparison of Treatment with Repetitive Transcranial Magnetic Stimulation Combined with Drug Therapy with Drug Therapy Alone in Post-Traumatic Stress Disorder

Public title

Repetitive Transcranial Magnetic Stimulation in Post-Traumatic Stress Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years old History of PTSD According to Beck Depression Inventory did not get a score above 17. At least four weeks (the minimum duration of drug effect) have elapsed since the start of drug treatment

Exclusion criteria:

Accompanied by other mental illnesses including depression History of epilepsy or seizures History of Drug Abuse History of severe head trauma or other severe neurosurgery complications Having any type of metal implant Using Pace Receive any type of electroconvulsive therapy for the past 6 months Current pregnancy Receive CBT (cognitive-behavioral therapy) at the same time with the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is three-blind and each patient receives a code and both RTMS and SHAM are performed by one of the nurses. The main collaborators of the project and the patients and the person who finally analyzes the results are all unaware of which patient is in which group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin university of Medical Sciences

Street address

Qazvin university of medical science, Shahid Bahonar blvd.

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

14002510

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Post-traumatic stress disorder score based on CAPS questionnaire

Timepoint

Weeks 0, 2, 4 and 8

Method of measurement

CAPS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group or A: Group of patients with post-traumatic stress disorder Simultaneously with taking the drug were treated with r-TMS at a frequency of 1 Hz for 20 minutes with an interval of one day for 15 weeks in 15

sessions.

Category

Treatment - Devices

2

Description

Control group or B: Group of patients with post-traumatic stress disorder who Simultaneously with drug treatment with standard drug regimen were treated with sham for 20 minutes at intervals of one day for three weeks in 15 sessions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Marjan Mahmoudian

Street address

22 Bahman Hospital, Railway Street, Nurse Alley

City

Qazvin

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3416899198

Phone

+98 28 3355 5054

Email

Marjanmahmudian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Emamjomeh

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Marjan Mahmudian

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Seyed Mohsen Zamir

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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

Information about main outcome and results

When the data will become available and for how long

Late 1400

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For scientific exploitation

From where data/document is obtainable

Marjan Mahmoudian/Marjanmahmudian@gmail.com

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

Send an email explaining the reason for the request

Comments