

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Therapeutic effect comparison of the Repetitive Transcranial Magnetic Stimulation (RTMS) combination therapy with drug versus medication monotherapy in obsessive compulsive disorder (OCD)

Protocol summary

Study aim

evaluate the efficacy (rTMS) as an adjunct therapy in combination with medication and localization in Iranian patients.

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment. Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Settings and conduct

Patients with a history of OCD who referred to the 22-Bahman Hospital's Psychiatric Clinic were interviewed by a psychiatrist who had DSM5 diagnostic criteria for obsessive-compulsive disorder

Participants/Inclusion and exclusion criteria

age 18-60 years History of moderate to severe persistent OCD The subjects did not score above 17 according to the Beck Depression questionnaire Exclusion criteria association with other psychiatric illnesses, history of epilepsy history of drug abuse history of neurosurgery complications having any type of metal implant

Intervention groups

Group A was treated with(rTMS) for 5 days (5,200 pulses / day) for 3 weeks at the same time as taking the drug While patients in group "B" were only treated with standard medication and sham was used for them so that the device was placed on their scalp without magnetic stimulation

Main outcome variables

Severity of obsessive-compulsive disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048240N1**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **retrospective**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Adeleh Askaridjarjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3355 5054

Email address

a.askaridjarjani@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-04-23, 1397/02/03

Actual recruitment start date

2018-05-26, 1397/03/05

Actual recruitment end date

2019-01-30, 1397/11/10

Trial completion date

2019-01-30, 1397/11/10

Scientific title

Therapeutic effect comparison of the Repetitive Transcranial Magnetic Stimulation (RTMS) combination therapy with drug versus medication monotherapy in obsessive compulsive disorder (OCD)

Public title

Effect of Repetitive Trans cranial Magnetic Stimulation (r-TMS) in treatment of obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-60 years History of moderate to severe persistent OCD (score greater than or equal to 16 in the Y-BOCS questionnaire) Score of the Beck Depression questionnaire below of 17 Receiving standard OCD medication through four weeks.

Exclusion criteria:

History of epilepsy or seizures History of drug abuse History of severe head trauma Having any type of metal implant or pace maker

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To perform randomization, participant included based on numbers of boxes which randomized based on the table one by one.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.

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 Science

Street address

Rahahan, Ave22, Bahman Hospital

City

Qazvin

Province

Qazvin

Postal code

3416899198

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.QUMS.REC.1396.63

Health conditions studied

1

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Severity of OCD

Timepoint

0, 1, 2, 3 weeks

Method of measurement

Yale-Brown OCS

Secondary outcomes

empty

Intervention groups

1

Description

Group A was treated with magnetic resonance imaging (rTMS) at low frequency (1 Hz) for 20 minutes daily for 5 days (5,200 pulses / day) for 3 weeks at the same time as taking the drug

Category

Treatment - Devices

2

Description

Control group:patients in group "B" were only treated with standard medication with the diagnosis of a psychiatrist and sham was used for them so that the device was placed on their scalp without magnetic stimulation

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Adeleh Askaridiarjani

Street address

Rah ahan Ave22 bahman Hospital

City

Qhazvin

Province

Qazvin

Postal code

3416899198

Phone

+98 28 3355 0254

Email

a.askaridiarjani@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Emamjomeh

Street address

Rah ahan Ave22 bahman Hospital

City

Qhazvin

Province

Qazvin

Postal code

3416899198

Phone**Email**

a.askaridiarjani@qums.ac.ir

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

Adeleh Askaridiarjani

Position

Psychiatrist, Department of Psychiatry, Qazvin University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Rah ahan Aven 22 Bahman Hospital

City

Qhazvin

Province

Qazvin

Postal code

3416899198

Phone

098 28 33550254

Email

a.askaridiarjani@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Alireza Haji Seyed Javadi

Position

Associate Professor, Psychiatrist, Department of Psychiatry, Qazvin University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Rah ahan Aven 22 Bahman Hospital

City

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Phone

098 28 33550254

Email

a.askaridiarjani@qums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

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Position

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Email

a.askaridiarjani@qums.ac.ir

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

Not applicable

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

Data about main outcome of study will be published

When the data will become available and for how long

2022

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For scientific goals

From where data/document is obtainable

Dr Adele Askaridiarjani: a.askaridiarjani@qums.ac.ir

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

Sending an E-mail and reason of request

Comments