

# 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**

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**Postal code**

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**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

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**Postal code**

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**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

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## 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**

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**Other areas of specialty/work**

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

Qazvin University of Medical Sciences

**Full name of responsible person**

Adeleh Askaridiarjani

**Position**

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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**

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**