

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment with Repetitive Trans cranial Magnetic Stimulation with medication, with medication alone in obsessive-compulsive disorder resistance to medication

Protocol summary

Study aim

Comparison of treatment with Repetitive Trans cranial Magnetic Stimulation with medication, with medication alone in obsessive-compulsive disorder

Design

Study was performed as a triple blind clinical trial on all patients with OCD with incidence criteria. At first, patients completed the Yale Brown YBOCS questionnaire. Patients with a score of 16 or older and without depression are enrolled in the study. A total of 30 patients are selected and are assigned to one of two groups, A or B, by randomized block design. Group A receive simultaneously with drug therapy for 3 weeks and 5 times per week with a frequency of 1 Hz for 20 minutes (1200 pulses / day) and patients in Group B are treated with drugs, but SHAM is used for them, that is, a device with no magnetic stimulation on the head. At the end of each week, patients again fill out the YBOCS questionnaire. At the end of the study, the mean scores of the questionnaire, as well as the clinical observations and clinical assessments of the questioner, were compared in both groups compared to the beginning of the study and the other group in order to determine the effectiveness of each regimen independently and in comparison with others as well as the rate of remission.

Settings and conduct

A triple blind clinical trial on all patients with OCD

Participants/Inclusion and exclusion criteria

Inclusion criteria: A previous history of OCD; In the YBOCS questionnaire, the score more than or equal to 16, and in the Beck questionnaire the score was not higher than 17. Exclusion criteria: History of seizure or epileptic seizures; History of severe head trauma or severe neurological complications.

Intervention groups

Group A: Therapeutic drug for 3 weeks and 5 times per week with a frequency of 1 Hz for 20 minutes (1200

pulses / day) Group B: Therapeutic drug plus SHAM

Main outcome variables

Improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190622043979N1**

Registration date: **2019-06-26, 1398/04/05**

Registration timing: **prospective**

Last update: **2019-06-26, 1398/04/05**

Update count: **0**

Registration date

2019-06-26, 1398/04/05

Registrant information

Name

Alireza Haj Seyed Javadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 5800

Email address

ahsjavadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment with Repetitive Trans cranial Magnetic Stimulation with medication, with medication alone in obsessive-compulsive disorder resistance to medication

Public title

Comparison of treatment with Repetitive Trans cranial Magnetic Stimulation with medication, with medication alone in obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-60 A previous history of OCD for at least one year, treated with the first two Obsessive drugs approved by the FDA, has not been improved and is right-handed. In the YBOCS questionnaire, the score was more than or equal to 16, and in the Beck questionnaire the score was not higher than 17.

Exclusion criteria:

Accompanied with other psychiatric disorders History of seizure or epileptic seizures Beck questionnaire score above 17 Pregnancy Substance abuse based on biographie History of severe head trauma or severe neurological complications Metal implant or pace maker

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is done using block method. Unit of randomization is individual. Randomization is done using a table of random numbers and to generate random sequences as online, computer is used. For concealing treatment allocation, the list of treatments are placed in the enclosed and numbered (to maintain order of sequences) envelopes .

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is triple blind, and each patients receive a code, whether RTMS or SHAM is done by one of the nurses. Main contributors to the project, and the patients and the one who finally analyzes the results, all of them

are not aware of patients assignment to 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 Sciences

Street address

Shahid Bahonar Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2019-02-20, 1397/12/01

Ethics committee reference number

IR.QUMS.REC.1397.357

Health conditions studied**1****Description of health condition studied**

Obsessive compulsive disorder resistance to drug therapy

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes**1****Description**

Improvement

Timepoint

Obsessive compulsive disorder will be assessed in both groups of A and B after 3 weeks.

Method of measurement

At the end of the study, the mean scores of the questionnaire, as well as the clinical observations and clinical assessments of the questioner, were compared in both groups compared to the beginning of the study and the other group in order to determine the effectiveness of each regimen independently and in comparison with others as well as the rate of remission

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Therapeutic drug for 3 weeks and 5 times per week with a frequency of 1 Hz for 20 minutes (1200 pulses / day)

Category

Treatment - Drugs

2

Description

Control group: Therapeutic drug plus SHAM (placement of the device without magnetic stimulation on the head)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Ghazal Jahanbakhsh

Street address

Rah ahan street, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Amir Peymani

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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

Ghazal Jahan Bakhsh

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Full name of responsible person

Alireza Haj Seyed Javadi

Position

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Specialist

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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