

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Repetitive Transcranial Magnetic Stimulation in the Treatment of Patients With Treatment Non-Response Obsessive-Compulsive Disorder

Protocol summary

Study aim

Determining the therapeutic effect of recurrent transcranial magnetic stimulation of the brain with a frequency of 1 Hz and LDLPFC target in patients with obsessive-compulsive disorder without response to drug therapy

Design

Clinical trial with control group, double-blind, randomized phase 2-3 on 32 patients. Random number table was used for randomization.

Settings and conduct

A double-blind clinical trial on patients with obsessive-compulsive disorder without response to treatment among outpatients admitted to Shahid Beheshti Hospital. Blindness is based on a random number table, and the therapist and patient are unaware of those who are blind. The study is performed in two groups and 16 patients in each group. The first group will receive effective nausea and the second group ineffective mobility, and the Yale Brown, Hamilton Anxiety, and Depression Questionnaires will be completed three times, the day before hospitalization, the day after treatment, and three months later during the interview.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People over 18 years of age and right-handed with a diagnosis of moderate to high OCD on the YBOCS scale who have not responded to at least two first-line drugs despite a sufficient dose and 12-week course of treatment. Exclusion criteria: Comorbidity with other psychiatric disorders except major depressive disorder, seizures, pregnancy, unstable medical conditions, cerebral metal implants, pacemaker, inner ear prosthesis

Intervention groups

The first group will receive 1 Hz stimulation on the lateral dorsal lateral cortex (L-DLPFC) and the second group will receive ineffective stimulation on the same area. They

will receive 20 sessions twice a week and 3 times a week.

Main outcome variables

Symptoms of obsessive-compulsive disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210818052221N1**

Registration date: **2021-10-18, 1400/07/26**

Registration timing: **prospective**

Last update: **2021-10-18, 1400/07/26**

Update count: **0**

Registration date

2021-10-18, 1400/07/26

Registrant information

Name

Javad Ghiami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3354 4001

Email address

ghiami.javad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Repetitive Transcranial Magnetic Stimulation in the Treatment of Patients With Treatment Non-Response Obsessive-Compulsive Disorder

Public title
Effectiveness of Repetitive Transcranial Magnetic Stimulation in Obsessive-Compulsive Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All persons over 18 years of age and right-handed who have complete diagnostic criteria for obsessive-compulsive disorder based on the diagnostic and statistical manual of mental disorders According to the standard Yale-Brown scale, the diagnosis of obsessive-compulsive disorder is moderate to high At least two first-line drugs for the treatment of obsessive-compulsive disorder have not responded despite a sufficient dose and 12-week course of treatment.
Exclusion criteria:
 Simultaneous onset of other psychiatric disorders based on diagnostic and statistical manual of mental disorders except major depressive disorder Seizures, pregnancy, unstable medical conditions Brain metal implants, pacemaker, inner ear prosthesis

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **32**
 More than 1 sample in each individual
 Number of samples in each individual: **3**
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Randomization (investigator's opinion)
Randomized

Randomization description
 Randomization of the study will be done with the help of a table of random numbers. Random number table is a set of numbers that is produced without a specific pattern or order and in a completely random way and has become a table. The pattern of reading the numbers from left to right will be determined and then the extracted even numbers will be assigned to the intervention group and the odd numbers will be assigned to the control group. This process will continue to reach the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description
 This study is double-blind and each patient receives a code and both rTMS and SHAM are performed by an rTMS specialist. The main collaborators of the project and the patients and all of them are 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 Zanzan University of Medical Sciences

Street address

Zanzan University of Medical Sciences, Azadi Square,

City

Zanzan

Province

Zanzan

Postal code

45156-13191

Approval date

2020-12-05, 1399/09/15

Ethics committee reference number

IR.ZUMS.REC.1399.312

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

Obsessive-compulsive score in the Yale-Brown questionnaire

Timepoint

Completion of the questionnaire of patients in both groups in three shifts, one day before the start of rTMS treatment, one day after the completion of the treatment period and after the quarterly follow-up

Method of measurement

Secondary outcomes

1

Description

Anxiety score

Timepoint

Completion of the questionnaire of patients in both groups in three shifts, one day before the start of rTMS treatment, one day after the completion of the treatment period and after the quarterly follow-up

Method of measurement

Hamilton Anxiety Questionnaire (HAM-A)

2

Description

Depression score

Timepoint

Completion of the questionnaire of patients in both groups in three shifts, one day before the start of rTMS treatment, one day after the completion of the treatment period and after the quarterly follow-up

Method of measurement

Hamilton Depression Questionnaire

Intervention groups

1

Description

Intervention group: A 1 Hz repetitive transcranial magnetic field will be performed on the lateral dorsal side of the left frontal cortex (L-DLPFC) for 20 sessions 3 times per week. In total, each intervention will last one month.

Category

Treatment - Devices

2

Description

Control group: Control group: Ineffective repetitive transcranial magnetic stimulation on the lateral dorsal side of the left frontal cortex (L-DLPFC) in 20 sessions 3 times per week. In total, each intervention will last one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Javad Ghiami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mina Shaabani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Zanjan University of Medical Sciences

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Javad Ghiami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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