

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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**

**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 Zanjan University of Medical Sciences

##### Street address

Zanjan University of Medical Sciences, Azadi Square,

##### City

Zanjan

##### Province

Zanjan

##### 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

Yale-Brown Questionnaire

## 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

##### Street address

Shahid Beheshti Hospital, Arg Square

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513615788

##### Phone

+98 24 3354 4001

##### Email

ghiami.javad@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Alireza Shoghli

##### Street address

Zanjan University of Medical Sciences, Azadi Boulevard

##### City

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##### Province

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##### Postal code

4515613191

##### Phone

+98 24 3315 6141

##### Email

research@zums.ac.ir

#### 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

**Street address**

Shahid Beheshti Hospital, Arg Square

**City**

Zanjan

**Province**

Zanjan

**Postal code**

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**Phone**

+98 24 3354 4001

**Email**

manaz@zums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Javad Ghiami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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

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Javad Ghiami

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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**Email**

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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