

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative effectiveness of transcranial Direct Current Stimulation (tDCS) in both PreSMA and LOF inhibition and comparing them with placebo in reducing symptoms in nonresponsive OCD patients

#### Protocol summary

##### Summary

Obsessive-Compulsive Disorder (OCD) is the fourth most common psychiatric disorder after phobias, substance abuse and Major Depressive Disorder (MDD). The lifetime prevalence of OCD is 2-3% in general population. About 10-40% of patients do not respond to routine treatments. tDCS or transcranial direct current stimulation is a new non-invasive brain stimulation compared with other non-invasive stimulation is a safe, low cost, simple design, deployment is easy and can be done in an outpatient clinic. This study is designed to study the effects of TDCS on reducing OCD symptoms in these patients. The target population are the outpatients with treatment-resistant OCD who will be chosen by a psychiatrist in Zare Hospital of Sari and based on the results drawn from the Yale-Brown Obsessive Compulsive Questionnaire (YBOCS). These patients between 18-60 years of age and at least 16 must be their test score and if they have other psychiatric illness, or not satisfactory they are excluded. In this study that designed double-blinded, 51 patients with treatment-resistant obsessive-compulsive disorder in three groups (two experimental groups and one placebo group) are matched for age and sex. And the severity of obsessive-compulsive symptoms before and after treatment and one month after treatment is evaluated on the basis of the questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201701095138N3**

Registration date: **2017-02-14, 1395/11/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-14, 1395/11/26

##### Registrant information

###### Name

Abbas Masoudzadeh

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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##### Recruitment status

###### Recruitment complete

##### Funding source

Research Assistance of Mazandaran University of Medical Sciences Dr. Ahmad Ali Enayati 2th BLD. Moallem SQ. Sari. Mazandaran IRAN

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative effectiveness of transcranial Direct Current Stimulation (tDCS) in both PreSMA and LOF inhibition and comparing them with placebo in reducing symptoms in nonresponsive OCD patients

##### Public title

Effectiveness of transcranial Direct Current Stimulation (tDCS) in Obsessive-Compulsive Disorder patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of OCD according to DSMV ; Lack of response to treatment with 2 drugs with sufficient dose and time (equal 80 mg Fluoxetine) ; Only this diagnosis in axis I and not have diagnosis in axis II ; Lack of drug dependence and lack of major neurological complications in terms of history; Written consent to participate in the study ; Right-handed ; Unchanged drug in the last month and the lack of psychotherapy in 8 weeks Exclusion criteria: Other disorders in axis I and II ; Having implant or prosthesis or metal in skull ; Patient satisfaction or waiver of him; Pregnancy

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **51**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of  
Medical Sciences

##### Street address

Moallem Sq.

##### City

Sari

##### Postal code

#### Approval date

2017-01-17, 1395/10/28

#### Ethics committee reference number

IR.MAZUMS.REC.95.1780

## Health conditions studied

### 1

#### Description of health condition studied

Obsessive-Compulsive Disorder

#### ICD-10 code

F 42.0

#### ICD-10 code description

These may take the form of ideas, mental images, or impulses to act, which are nearly always distressing to the subject. Sometimes the ideas are an indecisive, endless consideration of alternatives, associated with an inability to make trivial but necessary

## Primary outcomes

### 1

#### Description

Intensity of Obsession Compulsion Symptoms

#### Timepoint

Before intervention- after last intervention and 1 month after last intervention

#### Method of measurement

YALE-BROWN (Y-BOCS) Test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

17 patient in 10 days and every day 20 min treated with tDCS that cathode on left orbitofrontal region and anode on contralateral region with intensity 2mA

#### Category

Treatment - Devices

### 2

#### Description

17 patient in 10 days and every day 20 min treated with tDCS that cathode on left presupplementary motor area and anode on contralateral region with intensity 2mA

#### Category

Treatment - Devices

### 3

#### Description

17 patient in 10 days and every day 20 second treated with tDCS that cathode on left orbitofrontal region and anode on contralateral region with intensity 2mA

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Zare Hospital

**Full name of responsible person**

Dr. Abbas Masoudzadeh

**Street address****City**

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research of Mazandaran  
University of Medical Sciences

**Full name of responsible person**

Dr. Ahmad Ali Enayati

**Street address**

Moallem Sq.

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research of Mazandaran University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad Mehdi Rezaei

**Position**

Psychiatry Assistant

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*