

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

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Name of organization / entity

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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

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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

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

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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