Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Investigation the effect of transcranial direct current stimulation (tDCS) of the brain, as an adjunct to Fluexthine for patient with Obssesive-Compulsive Disorder: A clinical trial

Protocol summary

Summary

The aim of this study is to investigate the effect of transcranial direct current stimulation (tDCS) of the brain, on the symptoms of obsessive-compulsive disorder.In this regard, 60 patients with obsessive-compulsive disorder at psychiatric ward of Arak Amir-Kabir Hospital, will participate. After explaining the study, in case of their consent, demographic information will be received, and those with a score higher than 20 on the Yale-Brown and other criteria for inclusion and exclusion will be enrolled. The subjects will be randomly divided into two intervention and control groups. The anode electrode will be placed in the left dorsolateral cortex (pF3 point; 20/10 EEG), and the cathode electrode will be placed in the lateral side of right contralateral orbit (p8 point; 20/10 EEG). Patients will receive electrical stimulation with 2 mA, for 20 minutes (8 weeks, 3 sessions per week). The results of Yale-Brown Obsessive-Compulsive scale will be recorded before intervention, at 4, 8 and 12 weeks throughout the intervention. In the control group, situation is the same; with the exception that there is no stimulation. All patients are on Fluoxetine 40-80 mg.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030632904N1**
Registration date: **2017-07-14, 1396/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-14, 1396/04/23

Registrant information

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Name of organization / entity
Qom University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of transcranial direct current stimulation (tDCS) of the brain, as an adjunct to Fluexthine for patient with Obssesive-Compulsive Disorder: A clinical trial

Public title

The effect of electrical stimulation of the brain, in patients with obsession disorder

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: The Yale Brown score 20 or more; Age 20 to 60 years; Medication with Fluoxetine; Having at least primary education Exclusion criteria: Lack of cooperation during study despite adequate explanation; Having heart disease; Having neurological disease; Medication except Fluoxetine; Use of benzodiazepines and other antihistamines; ECT in the past two months; Existence of electronic devices and metal in the body; Exacerbation of disease and suicidal thoughts; Pregnancy; Having other psychiatric disorders; Having physical disease; Mental retardation; History of drug and alcohol abuse

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Subjects placed in two groups, using randomized block design.

Secondary Ids

1

Registry name
.

Secondary trial Id
.

Registration date
2017-11-22, 1396/09/01

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Vice chancellor for research, Arak University of Medical Sciences Complex, Basij Square

City
Arak

Postal code

Approval date
2016-11-21, 1395/09/01

Ethics committee reference number
IR.ARAKMU.REC.1395.9

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
Clinical feature of OCD

Timepoint
pre-intervention, at 4, 8 and 12 weeks throughout the intervention

Method of measurement
Yale-Brown Obsessive Compulsive Scale (YBOCS)

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Control group: Patients will attach through electrodes to the tDCS device, with 2 mA, for 20 minutes (8 weeks, 3 sessions per week); but stimulation will not be applied.

Category
Treatment - Devices

2

Description
Intervention Group: Transcranial direct electrical stimulation of the brain with 2 mA, for 20 minutes (8 weeks, 3 sessions per week) using tDCS device

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak Amir-Kabir Hospital, psychiatric ward

Full name of responsible person
Dr Bahman Salehi

Street address
Amir-Kabir Hospital, Parastar Square

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chanceller for research, Arak University of Medical Sciences

Full name of responsible person
Dr Mohammad Rafei

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Vice chanceller for research, Arak University of Medical Sciences Complex, Basij Square

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 chanceller for research, Arak 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
Arak University of Medical Sciences

Full name of responsible person
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Position
MA in Clinical Psychology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work

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Web page address

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