

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effectiveness of transcranial Direct Current Stimulation of the brain (tDCS) among people with Depressive Disorder

Protocol summary

Summary

The aim of the present study was to investigate the effects of daily transcranial direct current stimulation (tDCS) sessions in treatment of major depressive disorder. Twenty patients with major depressive disorder received 10 daily sessions of active or sham tDCS. Inclusion criteria: Diagnose of major depressive disorder; age over 18 years; lack of co-morbid disorders in axis I and II. Exclusion criteria: Other axis I or II comorbidity; mental retardation; substance abuse or dependence ; heart disease; a history of seizures and epileps; treatment failure of ECT for the current period of depression; pregnancy; medication concurrent. Change of the depression scores was assessed in before treatment, after acute treatment and one month after the end of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122525691N1**

Registration date: **2016-04-28, 1395/02/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-28, 1395/02/09

Registrant information

Name

negin Paast

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 88605323

Email address

dr.mrmozafari@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2016-08-25, 1395/06/04

Expected recruitment end date

2016-10-25, 1395/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of transcranial Direct Current Stimulation of the brain (tDCS) among people with Depressive Disorder

Public title

The effectiveness of transcranial Direct Current Stimulation of the brain (tDCS) among people with Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnose of major depressive disorder; age over 18 years; lack of co-morbid disorders in axis I and II. Exclusion criteria: Other axis I or II comorbidity; mental retardation; substance abuse or dependence ; heart disease; a history of seizures and epileps; treatment failure of ECT for the current period of depression; pregnancy; medication concurrent

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Single

Other design features

Meaning of placebo in this study was sham group that not receive tDCS treatment.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Qom University of Medical Sciences

Street address

Qom. Iran

City

Qom

Postal code

26184 06288

Approval date

2015-11-14, 1394/08/23

Ethics committee reference number

IR.MUQ.REC.021

Health conditions studied**1****Description of health condition studied**

Major Depressive Disorder

ICD-10 code

F30-F39

ICD-10 code description

This block contains disorders in which the fundamental disturbance is a change in affect or mood to depression (with or without associated anxiety) or to elation. The mood change is usually accompanied by a change in the overall level of activity; most of

Primary outcomes**1****Description**

The reduction in depression scores

Timepoint

Before treatment, after acute treatment, one month after the end of treatment

Method of measurement

Inventory

Secondary outcomes**1****Description**

The reduction in anxiety scores

Timepoint

Before treatment, after acute treatment, one month after the end of treatment

Method of measurement

Inventory

Intervention groups**1****Description**

Intervention group: tDCS was administered with DC-stimulator. Twenty minutes of 2 mA anodal and cathodal tDCS was delivered via two conductive rubber electrodes encased in saline soaked sponges (surface area 5 cm 7 cm) held in place with a broad flexible band. Anodal stimulation was delivered to the F3 (10-20 system) and cathodal to the supraorbital

Category

Treatment - Devices

2**Description**

Control group: The sham procedure consisted of an initial 30s ramp-in phase of active stimulation and 30→s a ramp-out phase.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ravan Isatis Counseling Center

Full name of responsible person

Negin Paast

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi (Deputy of Research and Technology)

Street address

1/1 Street, Fourth Street, No. 83, Department of Research and Technology Qom University of Medical Sciences, Iran, Qom, Safashahr.

City

Qom

Grant name

49616

Grant code / Reference number

Vice chancellor for research

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qom 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**

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Full name of responsible person

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Position

M.A clinical psychology

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Position

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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