

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of trans cranial direct current stimulation of the brain (TDCS) in patients with major depressive disorder referring

Protocol summary

Summary

The aim of this study was to investigate the effect of direct brain electrical stimulation (TDCS) in patients with major depressive disorder based on the criteria for entering the age of 18 to 65, both sexes have male and female, sixth grade primary education, no physical illness, other psychiatric disorders, family history of bipolar disorder, mental retardation, pregnancy after a clinical interview by psychologist and psychiatrist. The DSM-IV-TR diagnostic criteria and the score of over 18 in the Hamilton test are performed. Patients are randomly divided into case and control groups. In the control group, the SSRI drug is used and the electrodes are attached, but no electrical stimulation is performed. In the case group, in addition to the use of SSRI, electrodes are attached after preparing the subject, with the declaration of his readiness, a direct electric stimulation with a tDCS device with an intensity of 2 milliamperes is performed for 20 minutes per day during the week for 20 sessions. Hamilton test is repeated once before tDCS and then 4 weeks, 8 weeks, and 12 weeks after tDCS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101436756N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Bahman Salehi

Name of organization / entity

Arak University of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2016-06-26, 1395/04/06

Expected recruitment end date

2017-06-27, 1396/04/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of trans cranial direct current stimulation of the brain (TDCS) in patients with major depressive disorder referring

Public title

The effect of trans cranial direct current stimulation of the brain (TDCS) in patients with major depressive disorder referring!

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: aged 18 to 65 years; lack of psychotic diseases and synchronization with other disorders; lack of use; diagnosis of major depression based on clinical interview and diagnostic criteria of DSM IV Exclusion

criteria: Severe psychiatric disorders; Personality disorders; Consumption of multiple medications simultaneously; Severe physical illnesses; Recent use of warfarin, amoxicillin, ampicillin, theophylline, mycophenolate mofetil; Use of antidepressants in the last month; Pregnancy and lactation; Thoughts Suicide or harm to others; substance abuse and alcohol consumption

Age

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

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak, Sardasht, School of Medicine

City

Arak

Postal code

3819838453

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.ARAKMU.REC.1395.53

Health conditions studied

1

Description of health condition studied

depressive disorder

ICD-10 code

F33

ICD-10 code description

F33.0 , F33.1

Primary outcomes

1

Description

depression

Timepoint

Before tDCS and 4 weeks, 8 weeks and 12 weeks after tDCS

Method of measurement

Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Case group: In addition to using the SSRI drug, the electrodes are connected. After preparing the subject, he / she is prepared to direct the electric stimulation with a tDCS device with an intensity of 2 milliamperes for 20 minutes, one day per week for 20 sessions.

Category

Treatment - Other

2

Description

Control group: SSRI is consumed and electrodes are connected but no electrical stimulation is performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Dr. Farid Modirpoor

Street address

Amir Kabir Hospital, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Farid Modirpoor

Street address

Amir Kabir Hospital, Arak

City

Arak

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

Yes

Title of funding source

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

Dr. Farid Modirpoor

Position

Resident psychiatrist

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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