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 referringl

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
Araj

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
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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
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

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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