

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of trans cranial direct current stimulation of the brain(tdcs)on smoking cessation in patients with bipolar mood disorder in depressive phase

Protocol summary

Study aim

Evaluation of the effect of trans cranial direct current stimulation of the brain on smoking cessation in hospitalized patients with bipolar disorder

Design

This is a clinical trial study in which patients with bipolar disorder in the depressive phase referred to Amirkabir Hospital in Arak who meet the inclusion criteria are included in the study. In this study, 28 patients were randomly divided into intervention and control groups.

Settings and conduct

In this clinical trial study, patients with bipolar disorder in the depressive phase referred to Amirkabir Hospital in Arak are included in the study. In this study, 28 patients were randomly divided into intervention and control groups. In the intervention group, direct electrical brain stimulation was performed with tDCS device (with current of 2 mA for 20 minutes every day). In the control group, electrodes are attached to the patient's head but no stimulation occurs. Finally, the two groups are compared in terms of the severity of nicotine dependence symptoms (Nicotine Dependence Syndrome Scale Questionnaire) and the severity of depression (Montgomery-Asberg Depression Rating Scale).

Participants/Inclusion and exclusion criteria

Age 20-60 years, The existence of bipolar disorder criteria in the depression phase based on DSM V criteria, Lack of mental retardation, Lack of Epilepsy, dementia, delirium and other cognitive disorders, No Pregnancy, Lack of medical diagnosis has been shown to cause problems in the study process

Intervention groups

In the intervention group, transcranial direct current stimulation is performed with tDCS device (with the current of 2 mA for 20 minutes every day for 10 sessions) . In Control group: In this group, the electrodes of the TDCS device are connected to the head, but no

electrical stimulation takes place

Main outcome variables

The severity of nicotine dependence symptoms : Severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200614047771N1**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **retrospective**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

Registration date

2021-01-30, 1399/11/11

Registrant information

Name

arghavan zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3403 3094

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-12-21, 1399/10/01

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)on smoking cessation in patients with bipolar mood disorder in depressive phase

Public title
The effect of direct electrical stimulation of the brain on reducing smoking in patients with bipolar disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-60 years The existence of bipolar disorder criteria in the depression phase based on DSM V criteria Lack of medical diagnosis has been shown to cause problems in the study process
Exclusion criteria:
Pregnancy mental retardation Epilepsy, dementia, delirium and other cognitive disorders

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization using envelopes in the division of intervention and control groups - in this method, a number of cards or letters are selected by the researcher as the intervention group and the same number as the control group. The group related to each card It is written on it. These cards are in the envelope so that the group related to it is not specified. Then these letters were mixed and folded and then according to the order of patients entering the study, a card was issued for each patient and its allocation was recorded and the card was returned to all other cards after expiration. Then we mix and pick again and take out a new card for the next patient. This process continues until the last patient.

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

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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Province

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3848176941

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.ARAKMU.REC.1399.078

Health conditions studied

1

Description of health condition studied

bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

2

Description of health condition studied

Cigarette addiction

ICD-10 code

F17.21

ICD-10 code description

Nicotine dependence, cigarettes

Primary outcomes

1

Description

The severity of nicotine dependence symptoms

Timepoint

Nicotine dependence at the beginning of the study and after 10 sessions of tdcs

Method of measurement

Nicotine dependence syndrome scale(NDSS)

2

Description

Severity of depression

Timepoint

Severity of depression at the beginning of the study and after 10 sessions of tDCS

Method of measurement

Montgomery-asberg depression rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Both groups are treated with mood-stabilizing drugs (sodium valproate-lithium - antipsychotic) which are prescribed according to the patient's condition. In the intervention group, transcranial direct current stimulation is performed with tDCS device (with the current of 2 mA for 20 minutes every day for 10 sessions)

Category

Treatment - Devices

2

Description

Both groups are treated with mood-stabilizing drugs (sodium valproate-lithium - antipsychotic) which are prescribed according to the patient's condition. In the control group, electrodes of the TDCS device are attached to the head but no electrical stimulation takes place. Connected to the head, but no electrical stimulation takes place.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Amirkabir hospital

Full name of responsible person

Dr Anita Alaghemand

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Vice Chancellor for Education, Amir Kabir Hospital, Arak, Iran

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohsen Ghasemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When the article was out of print.

When the data will become available and for how long

After publishing the article

To whom data/document is available

University researchers

Under which criteria data/document could be used

If there are any further questions

From where data/document is obtainable

Dr Anita Alaghemand

What processes are involved for a request to access data/document

Letter writing should be done with professors and universities.

Comments