Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 brainon 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

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Iran (Islamic Republic of)

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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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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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Sponsors / Funding sources

1

Sponsor
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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
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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