

# 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)

##### Phone

+98 86 3403 3094

##### Email address

arghavan.dr13@yahoo.com

##### 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

##### City

Arak

##### Province

Markazi

##### Postal code

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

##### Street address

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

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3814957558

##### Phone

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

Vice chancellor for Research, Arak University of Medical Sciences, Basij Square, Arak, Iran

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arjmandzadegan@arakmu.ac.ir

#### 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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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Dr Anita Alaghemand  
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Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Psychiatrics  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
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Arghavan zarei  
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Medical doctor  
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Arghavan.dr13@yahoo.com

## 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