Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effect of transcranial Direct Current Stimulation on depressive symptoms in bipolar patients

Protocol summary

Study aim
The effect of transcranial electrical stimulation on depressive symptoms in adolescents with bipolar disorder

Design
This clinical trial has two groups: control and intervention. This is a randomized, double-blind, phase 2-3 study with 40 patients. Randomization will be done using random numbers created by the computer. The patient and the data analyzer are not aware of the type of intervention.

Settings and conduct
Qualified patients will be randomly divided into two intervention tDCS and control tDCS groups. Accidental randomization will be performed based on the randomization table. This clinical trial has a community-based, action-oriented control group with parallel and double-blind groups. The patient and the data analyzer do not know the type of intervention. This study will be done in Golestan hospital, Ahvaz

Participants/Inclusion and exclusion criteria
Included criteria: Having criteria for diagnosing bipolar disorder based on DSM-5 and approval of a psychiatrist; Being in a depressive phase based on DSM-5. Exclusion criteria: Existence of another associated psychiatric disorder based on a DSM-5; History of seizures other than seizures with fever; Patients requiring ECT and psychotic patients

Intervention groups
Intervention group: The true tDCS group will receive 2 sessions of the right anode and left cathode stimulation sessions by an experienced technician with no knowledge of the subject and an interventional therapist. The intervention will do randomly for 20 minutes and 2 mA on the lateral posterior frontal area Control group:Similar to the intervention group, the right anode and left cathode are placed on the patient's forehead by a specialist technician, without the knowledge of the subject and the experimenter, but the device will not turn on.

Main outcome variables
Symptoms of depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100520003979N11**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**
Update count: **0**

Registration date
2021-12-11, 1400/09/20

Registrant information

Name
Forugh Riahi

Name of organization / entity
Ahvaz Jundishapour University of Medical Sciences

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Iran (Islamic Republic of)

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+98 61 3374 3038

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riahi-f@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of transcranial Direct Current Stimulation on depressive symptoms in bipolar patients

Public title
The effect of transcranial electrical stimulation in bipolar disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having criteria for diagnosing bipolar disorder based on DSM-5 and approved by a psychiatrist Being in a depressive phase based on DSM-5
Exclusion criteria:
Existence of another associated psychiatric disorder based on a DSM-5 History of seizures other than seizures with fever Patients requiring ECT and psychotic patients
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using random numbers created by the computer. Random sequence generation software is used to generate numbers. Each random sequence is recorded on a card and the cards are sealed inside the envelope. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed..
Blinding (investigator's opinion)
Double blinded
Blinding description
The double-blind side includes the patient and the person who is responsible for analyzing the data. The patient knows that he has participated in a study but does not know what treatment is receiving. The person who is responsible for analyzing the data does not know which patient was involved in the intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan Blvd, Ahvaz, Khoozestan
City
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Postal code
6135715794
Approval date
2021-06-01, 1400/03/11
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.043

Health conditions studied

1

Description of health condition studied
Bipolar disorder
ICD-10 code
Bipolar di
ICD-10 code description
F31.9

Primary outcomes

1

Description
Depression symptoms
Timepoint
At the start of treatment, weeks 2, 4
Method of measurement
Hamilton Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The true tDCS group will receive 2 sessions of the right anode and left cathode stimulation sessions by an experienced technician with no knowledge of the subject and an interventional therapist. The intervention will do randomly for 20 minutes and 2 mA on the lateral posterior frontal area

Category
Treatment - Other

2

Description
Control group: the right anode and left cathode will place on the forehead by an experienced technician with no knowledge of the subject but the machine will not turn on.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry Clinic, Golestan Hospital
Full name of responsible person
Saeideh Farjadnia
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Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz
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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
Ahvaz 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
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Position
Associate Professor
Latest degree
Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available