# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Sep 2026

## Investigation of the effect of transcranial direct current stimulation on cognitive functions in patients with bipolar disorder

## Protocol summary

**Study aim**
Investigation of the effect of transcranial direct current stimulation on cognitive functions in patients with bipolar disorder

**Design**
Clinical trial on 42 patients, with parallel group, randomized and double-blinded

**Settings and conduct**
This study is performed on 42 patients with bipolar disorder in the euthemic phase referring to Ibn Sina Hospital and psychiatric clinics in Mashhad. The Young Mania Rating Scale is used for evaluation. Patients will then be randomly divided into control and intervention groups. In the intervention group, the anode is placed in the left prefrontal cortex and the cathode in the right cerebellar region at 2 mA for 20 minutes for three consecutive weeks. In the control group, the electrodes are arranged in the same way and will last as much as the intervention group but the electric current is cut off after 30 seconds. In this way, due patient and investigator not knowing about existence of electric current , the study will be double-blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: patients with bipolar disorder in the euthymic phase; not being in the manic and depression phase through analyzing the HDRS and YMRS questionnaires; patients must have disorders in several cognitive domains; the patient has no other psychiatric disorder or problem; the patient has not received shock therapy during the past year. Exclusion criteria: pregnancy and breastfeeding.

**Intervention groups**
In the intervention group, the anode is placed in the left prefrontal cortex and the cathode in the right cerebellar region (based on the 10/20 system) at 2 mA for 20 minutes for three consecutive weeks (5 working days). In the control group, the electrodes are arranged in the same way and will last as much as the intervention group but the electric current is cut off after 30 seconds.

**Main outcome variables**
Brain function and cognitive functions

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20101130005280N34**
Registration date: **2020-09-20, 1399/06/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-20, 1399/06/30**
Update count: **0**

**Registration date**
2020-09-20, 1399/06/30

**Registrant information**

**Name**
Raheleh Nejati

**Name of organization / entity**
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

**Country**
Iran (Islamic Republic of)

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nejatir2@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-07-05, 1399/04/15

**Expected recruitment end date**
2020-11-05, 1399/08/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigation of the effect of transcranial direct current stimulation on cognitive functions in patients with bipolar disorder

**Public title**
The effect of transcranial direct current stimulation on cognitive functions in patients with bipolar disorder
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with bipolar disorder in the euthymic phase between 18 to 42 years old No being in the manic and depression phase through analyzing the HDRS and YMRS questionnaires Patients must have disorders in several cognitive domains. The patient has no other psychiatric disorder or problem. The patient has not received shock therapy during the past year.
**Exclusion criteria:**
Pregnancy and breastfeeding
**Age**
From **18 years** old to **42 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **42**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple randomization with table of random numbers available at ''www.randomization.com'' website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Despite the use of electrodes for the whole 20 minutes, for patients in the control group, the electric current is cut off after 30 seconds. This is done to make the patient unaware of the existence of electric current. Also, the investigator is not aware of the presence of electric current. This way, the study will be double-blinded.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Mashhad University of Medical Sciences
**Street address**
Daneshgah street, Ghoreishi building
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
91778-99191
**Approval date**
2019-07-02, 1398/04/11
**Ethics committee reference number**
IR.MUMS.MEDICAL.REC.1398.618

## Health conditions studied

### 1

**Description of health condition studied**
Bipolar disorder
**ICD-10 code**
F31
**ICD-10 code description**
Bipolar disorder

## Primary outcomes

### 1

**Description**
Cognitive functions
**Timepoint**
At the beginning of the intervention, first, second, third and seventh week
**Method of measurement**
Stroop test

### 2

**Description**
Attention
**Timepoint**
At the beginning of the intervention, first, second, third and seventh week
**Method of measurement**
Digit span test

### 3

**Description**
Memory

**Timepoint**
At the beginning of the intervention, first, second, third and seventh week
**Method of measurement**
Rey auditory verbal Learning test and Rey–Osterrieth complex figure

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In this group, the anode is placed in the left prefrontal cortex and the cathode in the right cerebellar region (based on the 10/20 system) at 2 mA for 20 minutes for three consecutive weeks (5 working days)
**Category**
Treatment - Devices

### 2

**Description**
Control group: In this group, similar to the intervention group, the anode is placed in the left prefrontal cortex and the cathode in the right cerebellar region (based on the 10/20 system) at 2 mA for 20 minutes for three consecutive weeks (5 working days). But the electric current is cut off at second 30.This period of 30 seconds aims to make the patient unaware of whether there is electrical current or not.
**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ibn Sina Hospital
**Full name of responsible person**
Dr. Ali Talaei
**Street address**
Ibn Sinal Hospital, Horre Ameli boulevard, Bu Ali Square
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
91959 83134
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**Email**
talaeia@mums.ac.i

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr.Mohsen Tafaghodi
**Street address**
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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Razavi Khorasan
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9177899191
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+98 51 3841 2081
**Fax**
**Email**
ramresearch@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Ali Talaei
**Position**
Full professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Psychiatrics
**Street address**
Ibn Sinal Hospital, Horre Ameli boulevard, Bu Ali Square
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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talaeia@mums.ac.ir
**Web page address**

## 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**
All data can be shared after patients are made unidentifiable.
**When the data will become available and for how long**
Data can be accessible 6 months after results are published.
**To whom data/document is available**
Data can be accessible through an email to the corresponding author.
**Under which criteria data/document could be used**
Data will be available for researchers in universities and other scientific institutes.
**From where data/document is obtainable**
After sending a request email to the corresponding author, data will be sent in 1 month.
**What processes are involved for a request to access data/document**
Carrying out analysis on data is permitted.
**Comments**