Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 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)
Phone
+98 51 3711 2540
Email address
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
Phone
+98 51 3711 2709
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
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+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
City
Mashhad
Province
Razavi Khorasan

Postal code
91959 83134
Phone
+98 51 3711 2709
Email
talaeia@mums.ac.i

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. 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
City
Mashhad
Province
Razavi Khorasan
Postal code
91959 83134
Phone
+98 51 3711 2709
Fax
Email
talaeia@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. 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
City
Mashhad
Province
Razavi Khorasan
Postal code
91959 83134
Phone
+98 51 3711 2709
Fax
Email
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