Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The survey of transcranial direct current stimulation efficacy on the post-traumatic sleep quality, insomnia severity in the patients with mild traumatic brain injury during sub-acute phase

Protocol summary

Study aim
Effect of Transcranial direct-current stimulation (TDCS) in Recovery of Patients with Traumatic Brain Injury who had Insomnia

Design
A randomized double-blind clinical trial study of 64 patients with traumatic brain injury with subacute insomnia disorder who referred to Poursina Clinic and met the inclusion criteria of each group including 32 patients. 1- Get real tDCS 2- Get sham tDCS with medicine.

Settings and conduct
A randomized double-blind clinical trial study of 64 patients with traumatic brain injury with subacute insomnia disorder referred to Poursina Clinic. The intervener randomly selects the block and applies the assignment of the sample to the groups based on that block.

Participants/Inclusion and exclusion criteria
Inclusion: 18 to 65 years of age, brain scan findings, patency more than two weeks to one month after injury, ISI score up to 7 Exclusion: Sleep disorders, psychotropic medication one month before inclusion, neurological diseases, previous traumas, pregnant patients, pacemaker implants and psychoactive drugs, drug abuse,neurological diseases, history of seizures, tumor, neurotrauma, stroke,eczema of subdermal tDCS electrodes. Behavioral problems - Phenytoin, carbamazepine, verapamil, nimodepine and flunarzine, etc. - dissatisfaction

Intervention groups
2 intervention groups. Each group consisted of 32 subjects. 1-Get real tDCS 2-Get sham tDCS with medicine.

Main outcome variables
Insomnia severity index(ISI) Pittsburgh sleep quality index(PSQI)

General information

Reason for update

Acronym
tDCS-TBI

IRCT registration information
IRCT registration number: **IRCT20130416013027N2**
Registration date: **2019-12-23, 1398/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-23, 1398/10/02**
Update count: **0**

Registration date
2019-12-23, 1398/10/02

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-26, 1398/06/04

Expected recruitment end date
2020-05-09, 1399/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The survey of transcranial direct current stimulation efficacy on the post-traumatic sleep quality, insomnia severity in the patients with mild traumatic brain injury during sub-acute phase

Public title
The survey of transcranial direct current stimulation efficacy on the post-traumatic sleep quality, insomnia severity in the patients with mild traumatic brain injury during sub-acute phase

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients aged 18 to 65 years Normal and abnormal findings on brain scans within the first 24 hours of hospitalization all TBI severity at least 2 weeks to one month after the time of injury onset The ISI score is over 7 .

Exclusion criteria:
People with a history of primary sleep disorders taking psychotropic drugs one month before entering the study having serious neurological and psychiatric disorders patients with previous traumas those with tDCS contraception, such as pregnant patients, patients with metal implants or pains, those having a heart pacemaker, taking a psychoactive drug or an effective CNS drug, substance abusers, existence of psychiatric and neurological diseases , a history of seizure, epilepsy, tumor, Neurotrauma, stroke, or neurological diseases, those experiencing skin eczema under the tDCS electrodes Clinical instability or having behavioral problems that prevent the cooperation of the subject in the intervention The use of sodium and calcium-dependent calcium channel blockers such as phenytoin, carbamazepine, verapamil, nimesadine, and flonarazine having a serious complication associated with tDCS The patient's dissatisfaction with the continuation of the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples by are divided into two intervention groups by sealed envelope software using random blocks method including Four blocks. Each group includes 32 people. 1- A group receiving true tDCS 2- A group that receives tDCS plus medicine. The intervener randomly chooses a block and applies the assignment of the sample to the groups based on that block.

Blinding (investigator's opinion)
Double blinded

Blinding description
During blinding, an individual other than the patient's examiner sets the device for triggering or not, so the examiner and the patient are not known to be in the tDCS group or the sham.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Guilan University of Medical Sciences

Street address
namjoo ave-poursina hospital-way trauma research center

City
Rasht

Province
Guilan

Postal code
4193713194

Approval date
2019-07-17, 1398/04/26

Ethics committee reference number
IR.GUMS.REC.1398.182

Health conditions studied

1

Description of health condition studied
Insomnia in subacute traumatic brain injury

ICD-10 code
S06

ICD-10 code description
Intracranial injury

Primary outcomes

1

Description
The severity of insomnia disorder in patients with traumatic brain injury in subacute phase The score on the Insomnia Disorder Intensity Index (ISI) ranged from 0 to 28

Timepoint

Before starting study and one to three months after starting study

Method of measurement

ISI(Insomnia severty index)

2

Description

Sleep quality in patients with traumatic brain injury in subacute phase with a total score on the Pittsburgh Sleep Quality Index (PQQI) score between 0 and 21

Timepoint

Before starting study and one to three months after starting study

Method of measurement

PSQI(Pittsburg sleep quality index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:32 patients. The group receiving the actual tDCS. Anodal tDCS is performed on the right DLPFC and cathodal on the left shoulder with a 1.5 mA excitation intensity and a 15-min excitation duration over 15 weekly sessions of 5 consecutive sessions for three weeks.

Category

Treatment - Devices

2

Description

Control group:Includes 32 patients receiving sham tDCS with medication. In the control group, 30 seconds of electrical stimulation is applied and then discontinued. But they receive drug treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurosurgery Clinic of Poursina Hospital

Full name of responsible person

Zohair Reihanian

Street address

Parastar Ave-Imam reza treatment clinic of Poursina Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Web page address

http://www.gums.ac.ir/research/default.aspx?tabid=10362

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Zohair Reihanian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work
Neurosurgery
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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
Some information related to main outcome are provided
When the data will become available and for how long
6 months after summary data published
To whom data/document is available
Only academic researchers
Under which criteria data/document could be used
For the therapeutic decision making in clinic
From where data/document is obtainable
s.ramezanislp@gmail.com
What processes are involved for a request to access data/document
Between 1 to 2 month after request
Comments
I have no comment