# 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**

**Name**
Sara Ramezani Kapourchali
**Name of organization / entity**
Guilan Road Trauma Research Centre
**Country**
Iran (Islamic Republic of)
**Phone**
+98 13 1323 8373
**Email address**
s.ramezanislp@gmail.com

**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

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713194

**Phone**

+98 13 3332 2444

**Email**

pedramesmaily@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Shademan nemati

**Street address**

Namjoo Ave - Shahid Siadati Street

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713194

**Phone**

+98 13 3333 5821

**Fax**

+98 13 3333 6395

**Email**

nemati@gums.ac.ir

**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
**Street address**
Parastar Ave-PourSina Hospital-Trauma research center
**City**
Rasht
**Province**
Guilan
**Postal code**
4193713194
**Phone**
+98 13 3336 8773
**Fax**
+98 13 3331 1472
**Email**
zoheir.reihanian@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Rasht University of Medical Sciences
**Full name of responsible person**
Sara Ramezani
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Neuroscience
**Street address**
Parastar Ave-PourSina Hospital-Trauma Research Center
**City**
Rasht
**Province**
Guilan
**Postal code**
4193713194
**Phone**
+98 13 3336 8773
**Fax**
+98 13 3331 1472
**Email**
s.ramezanislp@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Rasht University of Medical Sciences
**Full name of responsible person**
Sara Ramezani
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Neuroscience
**Street address**
Parastar Ave-PourSina Hospital-Trauma Research Center
**City**
Rasht
**Province**
Guilan
**Postal code**
4193713194
**Phone**
+98 13 3336 8773
**Fax**
+98 13 3331 1472
**Email**
s.ramezanislp@gmail.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**
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