

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Transcranial direct-current stimulation(tDCS) on moral decision making in patients with traumatic brain injury

Protocol summary

Study aim

Evaluation of tDCS (transcranial direct current stimulation) effect on traumatic brain injuries patients

Design

Two arms parallel-group randomized trial with blinded outcome assessment

Settings and conduct

In Loghman hakim hospital ten session of tDCS in right dorsolateral prefrontal cortex will be done. ethical decision making test will be done after and before treatment but the researcher who do this evaluation is not aware of which person receive the tDCS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: traumatic brain injury base on brain CT scan (except occipital lobar injury; education: more than primary school; age (18-65); man and woman Exclusion criteria: any loss of consciousness or delirium base on clinical history; presence of aphasia; acute phase of mood or psychotic disorder base on semi-structure interview; acute phase of substance abuse; anti social, borderline or narcissistic personality disorder base on DSM5 SCID II semi-structure interview; severe cognitive disorder base on Montreal Cognitive Assessment score less than 10

Intervention groups

Traumatic brain injury patients are randomly divided into two groups: 1. Group 1 who receive tDCS and 2. group 2 who don't receive tCDS

Main outcome variables

Ethical decision making test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220531055042N1**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Hossein Pakdaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 0044

Email address

bmrc@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-11, 1401/04/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Transcranial direct-current stimulation(tDCS) on moral decision making in patients with traumatic brain injury

Public title

Transcranial direct-current stimulation(tDCS) on moral decision making in patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Brain trauma based on brain CT scan findings (other than injuries in the occipital lobe)

Exclusion criteria:

Any decrease in level of consciousness or delirium based on clinical history Existence of aphasia Acute mood or psychotic phase based on semi-structured interview '

Age

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

Gender

Both

Phase

0

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table Block random sampling will be used. In the present study, there are two groups (intervention group and control group). Therefore, four blocks will be used. According to the sample size (28 people in total, 14 in each group), 7 blocks of four will be considered. The random allocation of individuals to the group's understudy will be done as follows: First, there are 7 envelopes containing four cards with ABCD Latin letters, the letters A and B = the intervention group, the letters C and D = will be considered as the control group. According to the inclusion criteria, the patients were asked to choose one of the 7 seals envelopes randomly and select a random card from the inside, which is based on the card's adhesive that determines the allocation of the individual to either of the two study groups

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a single-blinded manner in which the evaluating researcher is not aware of which patients received the Transcranial direct-current stimulation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Loghman hakim Hospital, South Karegar St.

City

Tehran

Province

Tehran

Postal code

1764665645

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.067

Health conditions studied

1

Description of health condition studied

Neurology

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Ethical decision making

Timepoint

At the time of admission (before intervention) and after 30 days & 60 days after intervention

Method of measurement

Questionnaire (ethical decision making test)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: traumatic brain injury patients who received transcranial direct current stimulation. In Loghman hakim hospital ten session of tDCS (transcranial direct current stimulation) in 20 minutes in right dorsolateral prefrontal cortex will be done.

Category

Treatment - Other

2

Description

Control group: traumatic brain injury patients who do not receive treatment

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman hakim hospital

Full name of responsible person

Hossein pakdaman

Street address

Loghman hakim hospital, kamali Ave, South kargar, tehran

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1333631151

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hpakdaman@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein pakdaman

Street address

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein pakdaman

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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Person responsible for updating data

Contact

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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

Part of the data, which is the main consequence of the study

When the data will become available and for how long

Starting to access the data after 6 months of publishing the result

To whom data/document is available

researchers working in academic and industrial institutions

Under which criteria data/document could be used

Therapeutic usage

From where data/document is obtainable

Hossein pakdaman, hpakdaman@sbmu.ac.ir

What processes are involved for a request to access data/document

After submitting the request and checking the available items, the data is obtained

Comments