

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The evaluation of moral decision making and its coherence with risky decision making and Sociocognitive profile in the patients with brain injuries (traumatic and stroke), before and after Transcranial direct current stimulation (tDCS), in comparison to Sham group.

Protocol summary

Study aim

assessment of Transcranial direct current stimulation (tDCS) on moral decision making in aim to better understand Neuro-anatomic network of moral decision making in brain

Design

In this clinical trial, randomized controlled trial are conducted on total 20 individuals dividing into two groups of 10 for stimulation and 10 without any. Randomization is individualized and simple. Analyzers and participants are not informed about whether a person is in the control group or in the trial group.

Settings and conduct

patients would be first assessed in Rasoul and firoozgar hospitals then referred to brain clinic for intervention. participants and analyzers are blinded in this study.

Participants/Inclusion and exclusion criteria

inclusion criteria: finishing middle school. no sever behavioral problem interfering with the project. no physical restriction interfering with the project. good drug compliance. no substance use disorder in the last month. no change in psychiatric medication in last month. no psychiatric hospitalization in the last moth. exclusion criteria : delirium or decrease in level of consciousness in time of the project. prominent aphasia. acute mood or psychotic phase. schizophrenia. acute intoxication. severe cluster B personality disorder. sever cognitive impairment interfering with the project. uncontrolled seizure. neurosurgery of brain with prominent skull deficit. acute intracranial hemorrhage.

Intervention groups

we will use high definition transcranial direct current stimulation for the intervention group fulfilling inclusion criteria. Used protocol will be based on similar studies for

behavioral interventions. the placement of electrodes will be on dorsolateral prefrontal cortex. In control group in spite of electrode placement no stimulation is used.

Main outcome variables

moral decision making, empathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191016045135N1**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **retrospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Fatemeh Sadat Mirfazeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2331

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of moral decision making and its coherence with risky decision making and Sociocognitive profile in the patients with brain injuries (traumatic and stroke), before and after Transcranial direct current stimulation (tDCS), in comparison to Sham group.

Public title

impact of Transcranial direct current stimulation (TDCS) on moral decision making in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

finished middle school medication compliance no change in medication in last month no psychiatric hospitalization over the last month

Exclusion criteria:

decrease in level of consciousness prominent aphasia acute phase of mood or psychotic episode substance use disorder in the last month antisocial or borderline or narcissistic personality disorder severe cognitive impairment interfering cooperation in the intervention uncontrolled seizure active intracranial hemorrhage brain neurosurgery with prominent skull deficit schizophrenia diagnosis

AgeFrom **17 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

A number of 20 participants with moral decision making impairment in divided into two groups of 10 people based on simple randomization by table of random numbers. one group of 10 will receive sham while the other will receive TDCS.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the current study, participants are blind to the situation whether they are receiving electrical stimulation through tDCS or not. Before undergoing

tDCS, the process will be properly explained to the patients. For some patients the electrodes of tDCS will be placed on the scalp without any electrical stimulation. Data analyzer and outcome assessors are also unaware of which participant has received electrical stimulation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway

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Postal code

14665-354

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.IUMS.REC.1398.633

Health conditions studied**1****Description of health condition studied**

Traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

2**Description of health condition studied**

Brain stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes**1****Description**

Moral decision making score

Timepoint

Before intervention and within 1 hour of intervention

Method of measurement

Moral vignettes prepared by Knutson et al

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: will receive Transcranial direct current stimulation (tDCS).

Category

Treatment - Devices

2**Description**

Control group: Sham: the electrodes of tDCS device will be placed on the skull of this group without any electrical stimulation.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul-Akram Hospital

Full name of responsible person

Fatemeh Sadat Mirfazeli

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2**Recruitment center****Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Abbas motevalian

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Iran University of Medical Sciences, Shahid Hemmat
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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Mirfazeli

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not 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

only a part of data like main outcome measures

When the data will become available and for how long

6 months after publication providing the journal editors agree on that.

To whom data/document is available

only for academic researchers

Under which criteria data/document could be used

it is allowed for analysis in meta -analysis articles

From where data/document is obtainable

Through email address mentioning phone complete Id and numbers , email address is necessary.

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

it will be sent within 1 month. but sending the identification and affiliation of the person is necessary.

Comments