

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of transcranial direct current stimulation on dorsolateral prefrontal cortex on BDNF, IL-6, TNF-alpha

Protocol summary

Study aim

Efficacy of transcranial direct current stimulation on dorsolateral prefrontal cortex on BDNF, IL-6, TNF- alpha

Design

After signing the consent form of participating in research, will randomly (on the web) be assigned in to three treatment groups (two real- stimulation groups and a sham group). The two real groups of 10 brain stimulation sessions in the DLPFC area and the sham group will receive 10 sham stimulation sessions in the same area.

Settings and conduct

After signing the consent form of participating in research, will randomly (on the web) be assigned in to three treatment groups (two real- stimulation groups and a sham group). The two real groups of 10 brain stimulation sessions in the DLPFC area and the sham group will receive 10 sham stimulation sessions in the same area.

Participants/Inclusion and exclusion criteria

Signing informed consent to participate in the research; Methadone treatment for at least two weeks before the intervention; age 18- 50 years old; minimum grade education. Exclusion criteria: absence of more than two sessions; suicidal thoughts or dangers that It is not possible to keep the dosage fixed; having severe psychiatric disorders such as schizophrenia; consuming multiple substance; history of injury to the head; history of epileptic seizures.

Intervention groups

Efficacy of transcranial direct current stimulation on dorsolateral prefrontal cortex on L-DLPFC, R-DLPFC and Sham.

Main outcome variables

Brain- derived neurotrophic factor (BDNF); interleukin 6 (IL-6); Tumor necrosis factor-(TNF-a); Quantitative EEG (QEEG); Desires for Drugs Questionnaire (DDQ); anxiety stress depression scale(DASS) and The ability to decision making

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033946N5**

Registration date: **2019-01-19, 1397/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**

Update count: **0**

Registration date

2019-01-19, 1397/10/29

Registrant information

Name

Mohsen Dadashi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3353 4500

Email address

mohsendadashi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of transcranial direct current stimulation on dorsolateral prefrontal cortex on BDNF, IL-6, TNF-alpha

Public title

Efficacy of transcranial direct current stimulation on dorsolateral prefrontal cortex on BDNF, IL-6, TNF-alpha

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent to participate in the research
Methadone treatment for at least two weeks before the intervention
Age 18- 50 years old
Minimum grade education

Exclusion criteria:

The absence of more than two sessions
Suicidal thoughts or dangers that It is not possible to keep the dosage fixed
Having severe psychiatric disorders such as schizophrenia
Consuming multiple substance
History of injury to the head
History of epileptic seizures

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

By online web software

Blinding (investigator's opinion)

Double blinded

Blinding description

Subjects will be evaluated by another examiner
Subjects will be assigned to groups without knowing about treatment groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

ZUMS Central Office: Azadi Square, Zanjan, Zanjan

City

Zanjan

Province

Zanjan

Postal code

45156-13113

Approval date

2018-08-14, 1397/05/23

Ethics committee reference number

IR.ZUMS.REC.1397.127

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

Mental and behavioural disorders due to use of opioids

ICD-10 code

F11.1

ICD-10 code description

Opioid abuse with opioid-induced mood disorder

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

Brain- derived neurotrophic factor (BDNF)

Timepoint

pretest-post test

Method of measurement

Eliza kit

Secondary outcomes**1****Description**

interleukin 6 (IL-6)

Timepoint

pretest-post test

Method of measurement

Eliza kit

2**Description**

Tumor necrosis factor-(TNF-a)

Timepoint

pretest-post test

Method of measurement

Eliza kit

3**Description**

Quantitative EEG (QEEG)

Timepoint

pretest-post test

Method of measurement

Mitsar set

4

Description

BART Impassivity

Timepoint

pretest- post test

Method of measurement

BART Impassivity questionnaire

5

Description

Craving

Timepoint

pretest- post test

Method of measurement

Desires for Drugs Questionnaire (DDQ)

6

Description

sub scale anxiety -DASS

Timepoint

pretest- post test

Method of measurement

depression sub scale(DASS)

7

Description

decision making ability

Timepoint

pretest-post test

Method of measurement

IUWA Gambling Task

Intervention groups

1

Description

Intervention group: There will be three groups. Two of them will be intervention groups and the other on will be sham group. One of the groups will receive Anodal tDCS treatment on R-DLPFC based on the protocol. This treatment consists of 10 sessions.

Category

Treatment - Devices

2

Description

Intervention group: This treatment consists of 6 sessions within two weeks. One of the groups will receive Cathodal tDCS treatment on L-DLPFC based on the protocol. This treatment consists of 10 sessions. This treatment consists of 6 sessions within two weeks.

Category

Treatment - Other

3

Description

Intervention group: The third group will sham tDCS but will be called the placebo effect of tDCS.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Behshti hospital

Full name of responsible person

Zakria Eskandari

Street address

Behshti hospital, Arq Square

City

Zanjan

Province

Zanjan

Postal code

45136-15788

Phone

+98 24 3354 4001

Fax

+98 24 3354 2403

Email

Mohsendadashi@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shogli

Street address

ZUMS Central Office: Azadi Square, Zanjan, Zanjan

City

Zanjan

Province

Zanjan

Postal code

45156-13191

Phone

+98 24 3354 4001

Fax

Email

Shogli@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Zakaria Eskandari
Position
ph.D student in adiction study
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Arq square-Beheshti hospital
City
Zanjan
Province
Zanjan
Postal code
45136-15788
Phone
+98 24 3354 4001
Email
mohsendadashi@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zakaria eskandari
Position
phd student in addiction study
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Arq squre- Beheshti hospital
City

Zanjan
Province
Zanjan
Postal code
45136-15788
Phone
+98 24 3354 4001
Email
Mohsendadashi@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zakaria Eskandari
Position
phd student in addiction study
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Arq square- Behshti hospital
City
Zanjan
Province
Zanjan
Postal code
4513615788
Phone
+98 24 3354 4001
Email
Mohsendadashi@zums.ac.ir

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

Not complete

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available