Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of transcranial direct current stimulation of dorsolateral prefrontal cortex on modulation of anxiety and craving in crystalline heroin dependents in MMT program.

Protocol summary

Summary

The present study is a semi-experimental, double-blinded, and cross over study with pre and post- test, and control group. The aim of the present study is to test the possibility of craving and anxiety reduction in crystalline heroin users in MMT program by (tDCS), on dorsolateral prefrontal cortex. Participants are the whole population of right- handed male crystalline heroin users in MMT program who were referred to drug addiction treatment and rehabilitation centers in Tehran. According to inclusion criteria, 40 people who get the highest marks in DDQ and HAMA will be selected based on available sampling method and they will be divided into experimental and control groups with 20 subjects in each, randomly. Sham stimulation will be applied for experimental group at first session. Anodal right and cathodal right tDCS will be apply for experimental group randomly during 2 sessions on their dorsolateral prefrontal cortex. To omit the carry over effect of multiple stimulations, the experiments will be performing at 72 hrs intervals. The control group will get the sham stimulation on the same spot for 20 min in 1 session. Drug Desire Questionnaire (DDQ) and Hamilton anxiety scale (HAMA) will be administered to all of the subjects, before initiation of the brain stimulation, and by the end of it. The data will be analyzed by use of covariance method by SPSS software for examining the reduction of anxiety and craving.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120625384N1**
Registration date: **2016-01-24, 1394/11/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-01-24, 1394/11/04

Registrant information

Name
Mona Sharifi Fardshad
Name of organization / entity
Islamic Azad University
Country
Iran (Islamic Republic of)
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behjoobraincenter@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator and Behjoo Brain Center

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-17, 1394/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of transcranial direct current stimulation of dorsolateral prefrontal cortex on modulation of anxiety and craving in crystalline heroin dependents in MMT program.

Public title

Efficacy of transcranial direct current stimulation in reduction of anxiety and crystalline heroin craving.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 25 to 50 year-old; right handed male; crystalline heroin smokers, with a history of at least 12 and at most 24 months of crystalline heroin dependence based on DSM-V criteria. Subjects at least have five years education, and are able to read, and understand the questions. Accept and sign the consent form.
Exclusion criteria: any current or past major clinical neurologic disorders; central nervous system-effective medication intake; history of epilepsy; brain surgery; brain tumor; intracranial metal implantation; clinically significant head trauma, or any major clinical psychiatric disorders (in axis I, except substance-related disorders).

Age
From **25 years** old to **50 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University Karaj Branch

Street address
Shahid Moazen and Esteghlal Blvd. Rajaei Shahr, Karaj

City
Rajaei Shahr

Postal code
313-31485

Approval date
2014-05-06, 1393/02/16

Ethics committee reference number
63820705922017

Health conditions studied

1

Description of health condition studied
Crystalline Heroin Dependence

ICD-10 code
F11

ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Anxiety

Timepoint
Before and after stimulation

Method of measurement
Hamilton Anxiety Scale

2

Description
Instant craving

Timepoint
Before and after stimulation

Method of measurement
Drug Desire Questionnair

Secondary outcomes

1

Description
tDCS side effects

Timepoint
After stimulation

Method of measurement
tDCS side effects check list

Intervention groups

1

Description
Direct current will be delivered from a constant current stimulator (ActivaDose), and will be transferred by a pair of (35 cm2) electrodes with stimulation intensity of 2mA. Electrodes are standard carbonic, covered with a normal saline soaked sponge cases. In current stimulations (right anodal/left cathodal), the anod electrod will be placed on the right DLPFC (F4), and the cathode electrod will be placed on the left DLPFC (F3). In current stimulations (right cathodal/left anodal), the cathod electrod will be placed on the right DLPFC (F4), and the anod electrod will be placed on the left DLPFC (F3). The stimulation will be performed randomly for subjects in the experimental group during 2 sessions. Subjects in experimental groups will receive sham stimulation at first

session. The only difference in this kind of stimulation is that the current will cut after 30s and primarily itching and sting will be felt by the subject. The Stimulation will be done for 20min. To omit the carry over effect of multiple stimulations, the experiments were performed at 72 hrs intervals.

Category

Treatment - Devices

2

Description

Direct current will be delivered from a constant current stimulator (ActivaDose), and will be transferred by a pair of (35 cm2) electrodes with stimulation intensity of 2mA. Electrodes are standard carbonic, covered with a normal saline soaked sponge cases. Subjects in control group will receive sham stimulation in 1 session. The only difference in this kind of stimulation is that the current will cut after 30s and primarily itching and sting will be felt by the subject. The Stimulation will be done for 20min.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Behjoo Brain Center

Full name of responsible person

Peyman Hassani Abharian

Street address

Sattarkhan After Asadi Street

City

Tehran

2

Recruitment center

Name of recruitment center

Taghdir

Full name of responsible person

Gite Ghorbani

Street address

Sadeghyeh Sazman-e- Aab Street 9th Strett

City

Tehran

3

Recruitment center

Name of recruitment center

Sayeh Center

Full name of responsible person

Dr. Nikbakht

Street address

Ferdos Blvd. Valiasr Strett Etemadian Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behjoo Brain Center

Full name of responsible person

Peyman Hassani Abharian

Street address

Sattarkhan Street, After Asadi Stret

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Behjoo Brain Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Behjoo Brain Center

Full name of responsible person

Peyman Hassani Abharian

Position

MD, PHD Cognitive Neuroscience

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty