

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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 Questionnaire

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 electrode will be placed on the right DLPFC (F4), and the cathode electrode will be placed on the left DLPFC (F3). In current stimulations (right cathodal/left anodal), the cathod electrode will be placed on the right DLPFC (F4), and the anod electrode 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

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City

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

Taghdir

Full name of responsible person

Gite Ghorbani

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3**Recruitment center****Name of recruitment center**

Sayeh Center

Full name of responsible person

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

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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

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

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Position

MD, PHD Cognitive Neuroscience

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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