

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Assessment of the effect of transcranial direct current stimulation on drug cue-induced craving in abstinent methamphetamine users using a visual paradigm and its prediction using resting state EEG signals

Protocol summary

Study aim

Assessment of tDCS effect on drug craving, ERP amplitudes and neuronal activity by a cue-induced craving paradigm in abstinent methamphetamine users. Predicting the tDCS effect on drug craving by rest EEG.

Design

Two arms parallel group, randomized, double-blind, sham-controlled trial. Randomisation will be carried out by Matlab software.

Settings and conduct

EEG will be recorded during 5 minutes eye open and 5 minutes eye closed Pre and Pos tDCS. A visual cue reactivity paradigm immediately before and after tDCS will be conducted to elicit ERPs. Immediate drug craving will be assessed at four-time points of pre and post tDCS. We will use Starstim to brain stimulation and g.Hlamp for EEG recording in National Brain Mapping Laboratory. A third party will select two codes for sham/active tDCS session, who will not involve in data acquisition and analyses due to tDCS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male; Age ≥ 18 and < 61 years old; Diagnosed with Methamphetamine Use Disorder; Positive response to Methamphetamine cue-reactivity screening. Abstinent from any drugs except cigarettes for at least one week. Exclusion criteria: Abstinence from methamphetamine for more than 6 months; History of major head trauma, seizure, brain surgery, intracranial metal implantation Positive drug test for amphetamines, opioids, cannabis confirmed by urine tests

Intervention groups

Participants randomly undergo one active (intervention group) or sham (control group) 2 mA-tDCS session.

Main outcome variables

The amplitude change of EAP, P3 and LPP and change of neuronal activities due to tDCs. Predicting The effect of tDCS on drug craving by rest EEG.

General information

Reason for update

Acronym

tDCS

IRCT registration information

IRCT registration number: **IRCT20170808035562N2**

Registration date: **2018-06-16, 1397/03/26**

Registration timing: **prospective**

Last update: **2018-06-16, 1397/03/26**

Update count: **0**

Registration date

2018-06-16, 1397/03/26

Registrant information

Name

Hassan Khajepour

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of transcranial direct current stimulation on drug cue-induced craving in abstinent methamphetamine users using a visual paradigm and its prediction using resting state EEG signals

Public title

Effect of transcranial direct current stimulation on drug craving of addicts

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Male gender Age ≥ 18 and < 61 years old Farsi speaking Diagnosed with Methamphetamine Use Disorder (last 12 months) based on Structured Clinical Interview for DSM-5 (SCID-5) Abstinent from any drugs except cigarettes for at least one week based on medical records or self-report, confirmed by urine analysis Positive response to Methamphetamine cue-reactivity screening (MCS) Willing and capable of interacting with the informed consent process⁸. The ability to understand, read and answer the tests

Exclusion criteria:

Unwillingness or inability to complete any of the major aspects of the study protocol, including drug cue rating, or behavioral assessment. Abstinence from methamphetamine for more than 6 months based on self-report Any major clinical psychiatric disorder, assessed by Structured Clinical Interview for DSM-5 (SCID-5) Active suicidal ideation with intent or plan determined by self-report or assessment by PI or study staff during the initial screening or any other phase of the study Positive drug test for amphetamines, opioids, cannabis confirmed by urine tests Any active skin disorder that affects skin integrity of the scalp Having any condition that would preclude undergoing a tDCS stimulation based on the tDCS safety checklist Unstable medical disorder reported in subject's medical history or by a clinician assessment History of major head trauma, seizure, brain surgery, intracranial metal implantation Non-correctable vision or hearing problems.

Age

From **18 years** old to **61 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants randomly undergo one active or sham tDCS

session. The randomization procedure will be performed by Matlab software. A binary random sequence with length 60 will be generated.

Blinding (investigator's opinion)

Double blinded

Blinding description

We will use STARSTIM for electrical brain stimulation located in National Brain Mapping Laboratory (NBML). This device has the capability to assign codes to different stimulation states (active and sham). One of NBML staffs who is not engaged in our project will select this codes. Participants, investigator, and data analyzer are uninformed that which code is related to sham or active states.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

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Tehran University of Medical Sciences , Pursina St, District 6, Tehran, Iran

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Approval date

2016-08-22, 1395/06/01

Ethics committee reference number

IR.TUMs.MEDICINE.REC.1395.1621

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

Methamphetamine dependence disorder

ICD-10 code

F11.2

ICD-10 code description

Opioid dependence

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

Amplitude of event-related potentials with middle latency (P3)

Timepoint

Immediately before and after intervention

Method of measurement

Event-related potentials will be recorded using a bio-signal amplifier with CE & FDA approval (g.Hlamp, g.tec company) from 62 scalp sites.

2

Description

Amplitude of event-related potentials with late latency (LPP)

Timepoint

Immediately before and after intervention

Method of measurement

Event-related potentials will be recorded using a bio-signal amplifier with CE & FDA approval (g.Hlamp, g.tec company) from 62 scalp sites.

3

Description

Amplitude of event-related potentials with early latency (<300 ms)

Timepoint

Immediately before and after intervention

Method of measurement

Event-related potentials will be recorded using a bio-signal amplifier with CE & FDA approval (g.Hlamp, g.tec company) from 62 scalp sites.

Secondary outcomes

1

Description

Functional brain connectivity

Timepoint

Before intervention-after intervention

Method of measurement

Weighted Phase Lag Index

2

Description

Effective brain connectivity

Timepoint

Before intervention-after intervention

Method of measurement

Granger causality method

3

Description

electric neuronal activities

Timepoint

Before intervention-after intervention

Method of measurement

Source reconstruction methods such as Standardized low-resolution brain electromagnetic tomography (sLORETA)

4

Description

Craving for Methamphetamin

Timepoint

Before, during & after

Method of measurement

Visual Analogue Scale (VAS)

5

Description

Craving for Methamphetamine

Timepoint

Before & after

Method of measurement

Desire for Drug Questionnaire

6

Description

Depression

Timepoint

After intervention

Method of measurement

Depression Anxiety and Stress Scale (DASS)

7

Description

Impulsivity

Timepoint

After Intervention

Method of measurement

Barratt Impulsiveness Scale

8

Description

Positive & Negative Affect

Timepoint

Before and After Intervention

Method of measurement

Positive and Negative Affect Scale

9

Description

Anxiety

Timepoint

After Intervention

Method of measurement

Depression Anxiety and Stress Scale (DASS)

10

Description

Stress

Timepoint

بفتق هدفثقرئدفعهذ

Method of measurement

Depression Anxiety and Stress Scale (DASS)

Intervention groups

1

Description

Intervention group: Direct current will be delivered using a StarStimCS system and transferred by a pair of circular stimulation electrodes with 1 cm radius. They have rear-fill apertures allows for gel supply.

Anode/cathode electrodes will respectively be placed over F3 and F4 electrodes (EEG 10/20 system) to target the right and left dorsolateral prefrontal cortex (rDLPFC). During anodal tDCS, a 2 mA current will be applied for 20 min.

Category

Treatment - Devices

2

Description

Control group: StarStimCS system with a pair of circular stimulation electrodes with 1 cm radius will be used. Anode/cathode electrodes will respectively be placed over F3 and F4 electrodes (EEG 10/20 system). The simulator will be turned off after a gradual ramping up of electrical current to 2 mA and down to 0 mA which took 1 min. The electrodes will be on the scalp for the remaining 18 min and subjects will not be informed that the device is turned off. After that, there will be again a gradual ramping up of electrical current to 2 mA and down to 0 mA which took 1 min.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Khaneh Dust Yaran Residential Center

Full name of responsible person

Ali Kaykani

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Hassan Khajehpour

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Medical Engineering

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Tehran University of Medical Sciences

Full name of responsible person

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Position

PhD candidate

Latest degree

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Other areas of specialty/work

Medical Engineering

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

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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