

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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  $\geq 18$  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 Khajehpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6646 6383

##### Email address

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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  $\geq 18$  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 process<sup>8</sup>. 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653861

**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 Methamphetamine

**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**

بفئق هءفئقرفءفهءء

**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

##### Street address

No.71, Shayan 1Alley, Persi Gas Ave, 17 Shahrivar Ave, Shad Abad Town, Tehran

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

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##### Web page address

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### 2

#### Recruitment center

##### Name of recruitment center

Peyrovan Hemat Reducing Damage Institute

##### Full name of responsible person

Hassan Jajuei

##### Street address

No.18, Taheri Alley, Javid Alley, Shahid Moradi Ave, Taavon Boulevard, Shahre Ziba Town, Tehran

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[info@phemat.ir](mailto:info@phemat.ir)

##### Web page address

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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

##### Street address

Medicine School, Tehran University of Medical Sciences, Pursina Ave, Keshavarz Bulevard, Tehran, Iran

##### City

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##### Province

Tehran

##### Postal code

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##### Fax

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##### Email

[s.akhond@neda.net](mailto:s.akhond@neda.net)

##### Web page address

##### 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

+98 21 6646 6383

**Fax****Email**

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**Web page address****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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**Web page address****Person responsible for updating data****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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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Street address**

Medical Physics and Biomedical Engineering  
Department, Medical School, Tehran University of  
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**City**

Tehran

**Province**

Tehran

**Postal code**

1417933331

**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