

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of Transcranial Direct Current Stimulation(tDCS) on craving, relaps and mental health parameters in Opioid patients under methadone maintenance treatment

Protocol summary

Study aim

The purpose of this study was to determine the rate of recovery of craving, relapse, depression, anxiety, stress and sleep quality in patients undergoing methadone maintenance therapy

Design

A clinical trial was conducted on 30 subjects in two groups of control and blinded, blind, randomized

Settings and conduct

Sampling will be done at addiction treatment centers of Mashhad University of Medical Sciences and patients who have had opioids and they are treated with methadone. subjects before the intervention, after the fourth and the last session of the intervention, are examined by the questionnaire's survey tool. The study is double-blinded.

Participants/Inclusion and exclusion criteria

inclusion criteria: Diagnosis of drug abuse and opiate dependence by a psychiatrist, Methadone intake in less than a year, having At least grade nine, completing Informed consent, aged 18-60 years exclusion criteria: Progressive disease such as diabetes, brain stroke and seizures. metal prostheses in skull. Having a heart pacemaker. Having psychotic diseases. abuse of other substances other than methadone. Reluctance to participate in research

Intervention groups

In intervention groups Fifteen subjects receive 7 sessions. 2 MA current for 20 minutes every other day in the F4 (anode) and F3 (cathode) regions of the skull, and Fifteen subject in control group receive the same current

Main outcome variables

Craving, relapse, depression, anxiety, stress, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180604039979N1**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-03, 1397/11/14**

Update count: **1**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-11, 1397/03/21

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Transcranial Direct Current Stimulation(tDCS) on craving, relaps and mental health parameters in Opioid patients under methadone maintenance treatment

Public title

The effect of tDCS on Opioid patients under methadone maintenance treatment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Detection of drug abuse and dependence on opioids under methadone maintenance treatment according to DSM-V diagnostic criteria by a specialist psychiatrist The patient only receives methadone treatment Methadone maintenance treatment for at least one year Have at least 9th grade literacy Complete informed consent Aged 18-60 years

Exclusion criteria:

Having any progressive disease, such as diabetes and neurological diseases, especially a history of head trauma and seizure Having metal objects or prostheses in head Having a shunt on the skull and pacemaker in the heart The presence of severe psychiatric illnesses in the I axis based on DSM-V diagnostic criteria: such as psychotic disorders Taking other medicines in addition to methadone (such as morphine, hashish, glass) Unwilling to participate in research

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects are randomly assigned to one of two study groups using the random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and researcher are blinded, but the research assistant is not blind. research assistant regulate device on real or sham mode in the case group or the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Biomedical Researches of Kashan Medical School

Street address

Gotbe Ravandi Boulevard

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kashan

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88715973474

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.009

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F11.14

ICD-10 code description

Opioid abuse with opioid-induced mood disorder

2

Description of health condition studied

Addiction

ICD-10 code

F11.182

ICD-10 code description

Opioid abuse with opioid-induced sleep disorder

Primary outcomes

1

Description

Reduce craving

Timepoint

Fourth and seventh session of intervention

Method of measurement

desire for drug questionnaire(DDQ)

2

Description

Reduce relaps

Timepoint

Fourth and seventh session of intervention

Method of measurement

Urine test

3**Description**

Reduce depression

Timepoint

Fourth and seventh session of intervention

Method of measurement

Depression, Anxiety and stress Scales (DASS-21)

4**Description**

Reduce anxiety

Timepoint

Fourth and seventh session of intervention

Method of measurement

Depression, Anxiety and stress Scales(DASS-21)

5**Description**

Reducing stress

Timepoint

Fourth and seventh session of intervention

Method of measurement

Depression, Anxiety and stress Scales(DASS-21)

6**Description**

sleep quality

Timepoint

Fourth and seventh session of intervention

Method of measurement

Pittsburgh Sleep Quality Index(PSQI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 7 sessions and receive tDCS electrical stimulation every two days. This electrical stimulation by the tDCS device at 2 mA for 20 minutes will be a right and left / left cathode assembly and will be applied using a pair of carbon electrodes of 35 cm² in area with a sponge pad covered with saline. Electrodeposition (positive) on the RightDLPFC (F4) and electrodes (negative) to be placed on left DLPFC(F3)

Category

Treatment - Other

2**Description**

Control group: Exactly for the control group, but, it is

performed as a sham and placebo

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ebne sina hospital

Full name of responsible person

Fatemeh Mharrari

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

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Full name of responsible person

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<http://research.kaums.ac.ir/Default.aspx?PageID=58>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Mohammad sadeghi bimorgh

Position

ph.D student

Latest degree

Master

Other areas of specialty/work

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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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The original outcome data can be shared

When the data will become available and for how long

Start the access period 12 months after publishing the results

To whom data/document is available

For scholars working in academia and academia

Under which criteria data/document could be used

Can be used for related studies

From where data/document is obtainable

sadeghi6637@yahoo.com Mohammad sadeghi bimorgh

What processes are involved for a request to access

data/document

The request is sent via email, sent within a maximum of

two weeks

Comments