Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 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

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mohammad sadeghi bimorgh

Name of organization / entity

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Iran (Islamic Republic of)

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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 truma 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

City
kashan

Province
Isfehan

Postal code
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 mAh 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
Kashan University of Medical Sciences
Full name of responsible person
Hmidi gholamali(ph.D)
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Web page address
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
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Person responsible for updating data

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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	two weeks
The request is sent via email, sent within a maximum of	**Comments**