

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison and Combination the effectiveness of transcranial direct current stimulation and varenicline on executive function, cravings, depression, anxiety and stress in smokers with major depressive disorder

Protocol summary

Study aim

Determining the amount of reduction of craving, depression, anxiety, executive function and improvement of negative affect through transcranial direct current stimulation and its synergistic effects with varenicline drug in depressed people dependent on nicotine smoking.

Design

Clinical trial with two intervention groups, one-blind, randomized, phase 2 on 100 patients who will be randomly assigned to two intervention groups.

Settings and conduct

Zanjan University of Medical Sciences, Shahid Beheshti Hospital, Vareniclin drug prescription, brain stimulation device, clients who smoke are assigned to two groups without knowing their placement.

Participants/Inclusion and exclusion criteria

1- Having the ability to give informed consent to participate in the research 2- Being at least 18 and at most 65 years old 3- Daily consumption of more than ten cigarettes for at least two years (14). 4- Non-use of other substances such as: methamphetamine, opioid and benzodiazepine (specified through clinical interview by Ballinger). 5- Having a diagnosis of major depression. 6- Failure to consider other severe psychiatric disorders

Intervention groups

smokers

Main outcome variables

Craving, negative emotion, anxiety, depression, improvement of executive functions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056816N1**

Registration date: **2023-02-12, 1401/11/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-12, 1401/11/23**

Update count: **0**

Registration date

2023-02-12, 1401/11/23

Registrant information

Name

zakaria eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-05-04, 1402/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison and Combination the effectiveness of transcranial direct current stimulation and varenicline on executive function, cravings, depression, anxiety and stress in smokers with major depressive disorder

Public title

effectiveness of transcranial direct current stimulation and varenicline on, executive function, cravings and, depression, anxiety and stress in smokers with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having the ability to give informed consent to participate in research Being at least 18 and at most 65 years old Daily consumption of more than ten cigarettes for at least two years(14) Non-use of other substances such as: methamphetamine, opioid and benzodiazepine (specified through clinical interview by Ballinger) Having a diagnosis of major depression Failure to consider other severe psychiatric disorders that will be screened through the structured interview of SKID

Exclusion criteria:

Consuming more than one marijuana cigarette per week Having a history of neurological diseases such as Parkinson's, epilepsy, convulsions, strokes and cardiovascular problems Having diseases related to the scalp Having a history of head trauma Presence of a device or tool in the head Exiting from the research after absence In two continuous sessions of treatment Pregnancy or breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done through simple random method using coin toss. In this way, subjects are randomly assigned to treatment and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done in such a way that the subjects and the therapist are not aware of the assignment to the groups and the statistical analyst will also be blind to the therapist and the subjects.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences Research Ethics Committee

Street address

Zanjan University of Medical Sciences-Shahid Beheshti Hospital, Department of Addiction Studies

City

Zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2022-12-13, 1401/09/22

Ethics committee reference number

IR.ZUMS.REC.1401.265

Health conditions studied

1

Description of health condition studied

People with smoking

ICD-10 code

Z72.0

ICD-10 code description

Tobacco use

Primary outcomes

1

Description

Decreasing score in depression, anxiety, stress Scale(DASS)

Timepoint

3 Month

Method of measurement

Dass questionnaire

2

Description

Decreasing score in mood profile

Timepoint

3 Month

Method of measurement

mood profile questionnaire

3

Description

Decreasing score in craving questionnaire

Timepoint

3 Month

Method of measurement

craving questionnaire

4

Description

Improving inhibition in Stroop test

Timepoint

3 Month

Method of measurement

Stroop software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: common protocol to reduce cravings in smokers through extracranial stimulation device (tDCS), placing the stimulating electrode (anode) on the right dorsolateral prefrontal cortex (DLPFC) and the inhibitory electrode (cathode), prefrontal cortex The dorsal side is left.

Category

Treatment - Other

2

Description

Intervention group: The use of varenicline is usually started as follows: the first three days, one tablet of 500 micrograms daily, days 4 to 7 one tablet (500 micrograms), from the 8th day onwards, one tablet of 1 mg twice a day. The complete period of taking varenicline is 12 weeks. It is possible that according to the doctor's opinion, in case of success in quitting smoking, it may continue for more than 12 weeks.

Category

Treatment - Drugs

3

Description

Intervention group: The protocol for the sham group is through the extracranial stimulation device (tDCS), placing the stimulating electrode (anode) on the right dorsolateral prefrontal cortex (DLPFC) and the inhibitory electrode (cathode) on the left dorsolateral prefrontal cortex. It runs for 40 seconds.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Davood Ahmadi

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Shahid Beheshti Hospital*Arg Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

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Research and Technology Unit Zanjan University of Medical Sciences -

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Eskandari Zakaria

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of each person's private data, the data is shared in the form of an article.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data and statistical analysis are shared through the article.

When the data will become available and for how long

2023

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

citing the source

From where data/document is obtainable

It is uploaded on scientific sites

What processes are involved for a request to access data/document

Through correspondence with the project manager's email

Comments

After the data is ready, the data will be shared with the article