

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of efficacy of Varenicline and transcranial direct current stimulation (tDCS) in smoke cessation

Protocol summary

Study aim

Comparison of the efficacy of varenicline and transcranial direct current stimulation (tDCS) in smoking cessation

Design

In this study, 106 smokers living in Arak will be divided into two equal groups of varenicline and TDCS using permuted block randomization method, considering inclusion and exclusion criteria.

Settings and conduct

The study is a randomized clinical trial. In this study, 106 patients will be divided into two completely equal groups of intervention and control. In the intervention group, 10 sessions of tDCS will be done with 2 milliampere stimulation for 20 minutes every day. In the control group, the varenicline tablets will be prescribed for 6 weeks, starting from half of milligram daily from the first day to 3rd and will be continued on the day 4th to 7th for half milligram every 12 hours, and 1 milligram every 12 hours from the 8th day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Smokers at the age of 18-65 Having a minimum literacy Informed consent Exclusion criteria: Request from the patient or the patient's legal guardian to leave the study Occurrence of harmful or intrusive side effects due to Varenicline or tDCS Contraindication of tDCS Epilepsy Dementia, delirium or other cognitive disorders Any history of psychiatric disorders Any history of attempting to smoke cessation including, Varenicline or Bupropion tablets, nicotine gum and nicotine patch

Intervention groups

The intervention group: In the intervention group, 10 sessions of 2 milliampere stimulation of tDCS will be done for 20 minutes every day. The control group: In the control group, the varenicline tablets will be prescribed for 6 weeks, starting from half of milligram daily from the first day to 3rd and will be continued on the day 4th to 7th for half milligram every 12 hours, and 1 milligram every 12 hours from the 8th day.

Main outcome variables

Severity of nicotine dependence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181026041468N4**

Registration date: **2021-08-11, 1400/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-11, 1400/05/20**

Update count: **0**

Registration date

2021-08-11, 1400/05/20

Registrant information

Name

Mehran Shayganfard

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3313 5075

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mshayganfard@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Varenicline and transcranial direct current stimulation (tDCS) in smoke cessation

Public title

Comparison of efficacy of Varenicline and transcranial direct current stimulation (tDCS) in smoke cessation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Smokers at the age of 18-65 Having a minimum literacy
Informed consent

Exclusion criteria:

Request from the patient or the patient's legal guardian to leave the study at any time of the study Occurrence of harmful or intrusive side effects due to Varenicline or tDCS Any contraindications of tDCS Epilepsy Dementia, delirium or other cognitive disorders Any history of psychiatric disorders Severe smoking Any history of attempting to smoke cessation including, Varenicline or Bupropion tablets, Nicotine gum and nicotine patch

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study restricted randomization method is used, which in order to create a balance in the samples assigned to each of the study groups, we will use the block randomization method with quadruple blocks. First the required blocks are numbered using a table of random numbers. Each block is assigned 2 samples for intervention and 2 samples for control. The samples for the intervention group (tDCS) are called A and the samples for the control group (receiving varenicline tablets) are called B. Then the sequence of these samples (A and B) for each block is determined using sequence generation software called (Random Allocation Software) RAS and finally based on the number of blocks and sequences assigned to each block is determined that Samples belong to intervention group A (tDCS) or control group B (receiving varenicline tablets). For concealment, blocking and allocation sequence is done by a person not involved in the research.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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Deputy of research and technology, Arak university of medical sciences, Payambar Azam university complex.

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Province

Markazi

Postal code

3848176341

Approval date

2021-04-21, 1400/02/01

Ethics committee reference number

IR.ARAKMU.REC.1400.005

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

Nicotine dependence

ICD-10 code

F17.21

ICD-10 code description

Nicotine dependence, cigarettes

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

Smoke cessation

Timepoint

Beginning and the end of the intervention

Method of measurement

Nicotine dependence scale (NDSS)

Secondary outcomes

empty

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

In the intervention group, 10 sessions of 2 milliampere stimulation of tDCS will be done for 20 minutes every

day.

Category

Treatment - Devices

2

Description

In the control group, the varenicline tablets will be prescribed for 6 weeks, starting from half of milligram daily from the first day to 3rd and will be continued on the day 4th to 7th for half milligram every 12 hours, and 1 milligram every 12 hours from the 8th day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital, Arak

Full name of responsible person

Seyed Vahid Mousavi

Street address

Amir Kabir hospital, Shahid Shiroudi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mehran Shayganfard

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

Statistical Analysis Plan

Not applicable

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