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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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
کمیته اخلاق دانشگاه علوم پزشکی اراک

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

City
Arak

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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381961187

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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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۳۸۱۹۶۹۳۳۴۵

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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

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Person responsible for updating data

Contact

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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