

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparing the effect of Varenicline tablet with correction of attention bias in smoking cessation

Protocol summary

Study aim

Comparing the effect of Varenicline tablet with correction of attention bias in smoking cessation

Design

In this study, 58 smokers living in Arak will be divided into two equal groups of Varenicline and correction of attention bias using permuted block randomization method, considering inclusion and exclusion criteria.

Settings and conduct

The study is a randomized clinical trial. In this study, 58 patients will be divided into two completely equal groups of intervention and control. In the intervention group, 12 sessions of correction of attention bias are performed with Dot prob task computer software 2 sessions per week. 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 18-60 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 attention bias. serve smoking.

Intervention groups

the intervention group : In the intervention group, 12 sessions of correction of attention bias are performed with Dot prob task computer software 2 sessions per week .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: **IRCT20181026041468N3**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **prospective**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Mehran Shayganfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 5075

Email address

mshayganfard@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-21, 1400/05/30

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Varenicline tablet with correction of attention bias in smoking cessation

Public title

Comparing the effect of Varenicline tablet with correction of attention bias in smoking cessation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Smokers at the age of 18-60 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 attention bias Severe smoker

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

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 (correction of attention bias) 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 (correction of attention bias) 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

Ethics committee of Arak university of medical sciences

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

2021-07-11, 1400/04/20

Ethics committee reference number

IR.ARAKMU.REC.1400.090

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 ,middle and the end of the intervention

Method of measurement

Nicotine dependence scale (NDSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 12 sessions of correction of attention bias are performed with Prob dot task computer software 2 sessions per week. Each session lasts 30 minutes, during which two visual stimuli randomly appear on the monitor screen, one with neutral content and the other with smoking stimulants . These images disappear after 600 milliseconds and a probe appears instead of one of the

two stimuli. What stimuli appear and which stimulus the probe replaces is randomly determined. This is repeated for other images, and the goal is to reduce the smoker's attention to cigarette-related stimuli, resulting in less smoking.

Category

Treatment - Devices

2

Description

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.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital, Arak

Full name of responsible person

Morteza Mehrmanesh

Street address

Amir Kabir hospital, Shahid Shiroudi St.

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mshayganfard@yahoo.com

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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Arak university of medical sciences, Sardasht

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alikalaliir@yahoo.com

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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Amirkabir hospital, Alamolhoda St.

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381961187

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Email

mshayganfard@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mehran Shayganfard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mehran Shayganfard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Amirkabir hospital, Alamolhoda St.

City

Arak

Province**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