

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Efficacy of Varenicline for smoking cessation among persistent smokers after coronary artery revascularization: A randomized placebo controlled clinical trial

Protocol summary

Study aim

The aim is to investigate the effect of Varenicline for smoking cessation in patients with coronary artery disease who continued smoking after coronary artery revascularization procedure

Design

A double-blind, randomized, placebo-controlled trial on 600 patients. A web-based randomization system will be used for randomization

Settings and conduct

The study will be conducted in Tehran Heart Center. Intervention will last for 13 weeks. All the participants will be followed up for 26 weeks after discontinuation of intervention to assess any ongoing abstinence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male sex ≥ 18 years old Current daily smoker of ≥ 5 cigarettes per day Having a history of coronary artery revascularization procedure 9-12 months prior to the study Able to consent to the study and to follow its instructions and procedures Exclusion criteria: 1- Unstable cardiac disease 2- Known case of dementia disorders such as Alzheimer 3- Known case of chronic renal failure 3- Known or suspected unstable psychiatric disorders that require acute medical treatment 4- Only one member of a household is permitted to participate in the trial concurrently to minimize cohort-confounding effects.

Intervention groups

The intervention group will receive Varenicline whereas the control group will be provided with placebo only. Patients in each arm will be instructed to use a 0.5 mg tablet (Varenicline/placebo) once daily for 3 days, a 0.5 mg tablet twice daily for 4 days and 1 mg tablet twice daily for remaining 12 weeks.

Main outcome variables

Between-group differences in the continuous abstinence rate at the end of 26 weeks follow up, the point

prevalence abstinence, prolonged abstinence rate, participation rate and amount of smoking.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200719048133N1**

Registration date: **2020-07-23, 1399/05/02**

Registration timing: **prospective**

Last update: **2020-07-23, 1399/05/02**

Update count: **0**

Registration date

2020-07-23, 1399/05/02

Registrant information

Name

Nazila Shahmansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9600

Email address

n.shahmansouri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Varenicline for smoking cessation among persistent smokers after coronary artery revascularization: A randomized placebo controlled clinical trial

Public title
Effect of Varenicline in smoking cessation after invasive treatment of coronary artery disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Male sex ≥ 18 years old Current daily smoker of ≥ 5 cigarettes per day Having a history of revascularization procedure for CAD in Tehran Heart 9-12 months prior to the study Able to consent to the study and to follow its instructions and procedures
Exclusion criteria:
 Unstable cardiac disease Known case of dementia disorders such as Alzheimer Known case of chronic renal failure Known or suspected unstable psychiatric disorders that require acute medical treatment Only one member of a household is permitted to participate in the trial concurrently to minimize cohort-confounding effects

Age
From **18 years** old

Gender
Male

Phase
4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **600**

Randomization (investigator's opinion)
Randomized

Randomization description
All of the participants will be assigned to either the intervention or placebo group. Block randomization with a variable block size of 2, 4, 6, 8, and 10 will be used for the allocation. A web-based randomization system will be used to generate randomization code by an independent researcher with no contact with the participants or other researchers.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The participants, the clinical practitioners, the nurse who will perform follow up contacts and the statistician who will analyses the data are all blinded during the clinical trial.

Placebo
Used

Assignment
Parallel

Other design features
Having coronary artery disease and performing invasive therapeutic interventions such as open heart surgery can increase a patient's motivation to quit smoking and cause them to quit smoking voluntarily. However, a considerable number of patients continue to smoke, regardless of the smoking role in subsequent cardiovascular events. The aim of this study is to evaluate the effectiveness of Varenicline in smoking cessation among patients who continue to smoke after experiencing open heart surgery or angioplasty treatment

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam Khomeini Hospital Complex, Tehran University of Medical Sciences

Street address

End of Keshavarz Boulevard, Dr. Gharib Street; Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.077

Health conditions studied

1

Description of health condition studied

Smoking cessation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Group differences in the continuous abstinence rate

Timepoint

Point prevalence abstinence at the end of 13 and 52 weeks of intervention.

Method of measurement

Self-reported rating scales that is confirmed by one of the close relatives who lives with patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this arm will be instructed to use Varenicline based on the following protocol: A 0.5 mg tablet once daily for 3 days, A 0.5 mg tablet twice daily for 4 days and 1 mg tablet twice daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients in this arm will be instructed to use placebo (identical tablets) based on the following protocol: A 0.5 mg tablet once daily for 3 days, A 0.5 mg tablet twice daily for 4 days and 1 mg tablet twice daily for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Masoumeh Lotfi Tokaldany

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Lotfi Tokaldany

Position

None academic specialist member

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific

inquiries

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Tehran University of Medical Sciences

Full name of responsible person

Saeed Sadeghian

Position

Associate professor

Latest degree

Subspecialist

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Position

None academic specialist member

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

Undecided - It is not yet known if there will be 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

Yes - There is 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

Title and more details about the data/document

Not applicable

When the data will become available and for how long

Not applicable

To whom data/document is available

Not applicable

Under which criteria data/document could be used

Not applicable

From where data/document is obtainable

Not applicable

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

Not applicable

Comments