

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Effectiveness of Atorvastatin on mortality and morbidity in catheterization procedures (Permcath)

Protocol summary

Study aim

Effectiveness of Atorvastatin on mortality and morbidity in catheterization procedures (Permcath)

Design

Clinical trial with control group and parallel groups, double blind, with using a permuted balanced block randomization method with the size of blocks 4 and 6, phase 3 on 228 patients, Random sequence will be generated by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

Settings and conduct

The aim of this study is evaluation of Atorvastatin effect on mortality and morbidity in catheterization procedures (Permcath). Locality of the study is in Amiralmomenin hospital of Arak city. Patients in statin group will receive Atorvastatin (Sobhan daru-Iran) 80 mg tablet 4 hours before surgery and 40 mg after surgery for 6 months daily. Patients in control group will receive the tablets with a similar shape of Atorvastatin 4 hours before surgery and in concomitant with patients in statin group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years old
Patients who have informed consent
Patients who need permanent dialysis
Sinus rhythm heart
Exclusion criteria: Patients with chronic atrial fibrillation (AF)
Patients with liver failure
Patients with using class I and III of anti-arrhythmic drugs
Patients with using corticosteroid drugs
Patients with history of statin use in control group

Intervention groups

Patients in statin group will receive Atorvastatin (Sobhan daru-Iran) 80 mg tablet 4 hours before surgery and 40 mg after surgery for 6 months daily. Patients in control group will receive the tablets with a similar shape of Atorvastatin 4 hours before surgery and in concomitant with patients in statin group.

Main outcome variables

Patients mortality rate- Cardiac arrhythmia and myocardial infarction- Catheter site infection- Catheter function and stenosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N10**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **prospective**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

Registration date

2021-11-16, 1400/08/25

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-18, 1400/08/27

Expected recruitment end date

2022-11-18, 1401/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Atorvastatin on mortality and morbidity in catheterization procedures (Permcath)

Public title

Effectiveness of Atorvastatin on reducing of death and illness after catheterization

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients older than 18 years old
Patients who have informed consent
Patients who need permanent dialysis
Sinus rhythm heart

Exclusion criteria:

Patients with chronic atrial fibrillation (AF)
Patients with liver failure
Patients with using class I and III of anti-arrhythmic drugs
Patients with using corticosteroid drugs
Patients with history of statin use in control group

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **228**

Randomization (investigator's opinion)

Randomized

Randomization description

Sequences web randomization (www.graphpad.com) dual group for creation of simple randomization and closed envelope method with random sequence (SNOSE) for concealment, will be used. Random sequences will be written on the cards and then sequentially put in the envelopes. In order to preserve random sequences, the outer surface of the envelopes are numbered, respectively. Finally, the lid of the envelopes will be pasted and placed inside the boxes, sequentially. At the time of participants registration, one of the envelopes will be open and the allocation group will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients have informed consent to entrance to study, but they do not know about the kind of drugs have been received. The required drugs will be prescribed by the cardiologist, but the person who will analysis the data of patients outcomes will be unaware about the patients group and the kind of received drugs.

Placebo

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

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2021-10-10, 1400/07/18

Ethics committee reference number

IR.ARAKMU.REC.1400.171

Health conditions studied

1

Description of health condition studied

Complications after permanent catheterization (permcath)

ICD-10 code

T82.8

ICD-10 code description

Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description

Frequency of cardiac arrhythmia

Timepoint

During 24 hours after catheterization

Method of measurement

Heart monitoring

2

Description

Frequency of myocardial infarction

Timepoint

During 24 hours after catheterization

Method of measurement

Heart monitoring

3

Description

Catheter site infection

Timepoint

Every 2 weeks till 6 month

Method of measurement

Physical examination

4**Description**

Catheter function

Timepoint

Every 2 weeks till 6 month

Method of measurement

Physical examination

5**Description**

Catheter stenosis

Timepoint

Every 2 weeks till 6 month

Method of measurement

Physical examination

6**Description**

Mortality

Timepoint

During 24 hours after catheterization

Method of measurement

Number

Secondary outcomes

empty

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

Intervention group: Patients will receive Atorvastatin (Sobhan daru-Iran) 80 mg tablet 4 hours before surgery and 40 mg after surgery for 6 months daily.

Category

Prevention

2**Description**

Control group: Patients will receive the tablets with a similar shape of Atorvastatin 4 hours before surgery and in concomitant with patients in statin group.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

Elham Farahani

Street address

Amiralmomenin hospital street, Basij square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3601

Email

farahani13025@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

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

Reza Shojaee

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Valie-asr square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

dr.reza.shojaee@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Elham Farahani

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Parastar square, Rah-ahan square, Shiroudi street

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 4715

Email

farahani13025@gmail.com

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

Arak University of Medical Sciences

Full name of responsible person

Shamim Valibak

Position

General physician non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Valiasr hospital, Valiasr square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

0098 86 32222003-8

Email

sh.valibak@yahoo.com

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

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