

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of atorvastatin and aspirin on the durability and performance of tunneled catheters in patients who are candidates for central venous catheter insertion for dialysis.

Protocol summary

Study aim

Comparison of the effect of atorvastatin and aspirin on the durability and performance of tunneled catheters in patients who are candidates for central venous catheter insertion for dialysis.

Design

The present study is a clinical trial with a control group, with parallel groups, randomized (using block randomization), phase 3 on 162 patients.

Settings and conduct

In this double-blind randomization clinical trial, patients who are candidates for tunneled central venous catheters referring to Amir al-Momenin Hospital in Arak will be divided into three equal groups of Atorvastatin, aspirin, and control by means of block randomization. In this study, patients (by placebo pills) and outcome assessors (by patient coding) will be blinded. In each group, drug treatment will be prescribed daily for 6 months. Finally, three groups will be evaluated in terms of study results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidates for central venous catheterization for whom a tunneled catheter will be implanted, having consent to participate in the study.
Exclusion criteria: the presence of a history of coagulation diseases, the presence of a disease that has contraindications for taking aspirin (such as nasal polyp disease, asthma, allergy to aspirin).

Intervention groups

Atorvastatin group: daily consumption of one 40 mg Atorvastatin tablet from Soban Daru Company from the day of catheter placement until 6 months or catheter removal. Intervention group: daily consumption of an 80 mg aspirin tablet from Galenos company from the day of catheter placement until 6 months or catheter removal. Control group: daily use of placebo tablets for 6 months

Main outcome variables

Duration of catheter operation, catheter infection, thrombosis, 180 days operation.

General information

Reason for update

The age range has changed from 20-55 years to 20-65 years.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N20**

Registration date: **2024-03-28, 1403/01/09**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-06, 1403/01/18**

Update count: **1**

Registration date

2024-03-28, 1403/01/09

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-12, 1402/12/22

Expected recruitment end date

2024-07-12, 1403/04/22

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of atorvastatin and aspirin on the durability and performance of tunneled catheters in patients who are candidates for central venous catheter insertion for dialysis.

Public title
Investigating the effect of atorvastatin and aspirin on the durability and function of the central venous catheter for dialysis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients for central venous catheterization, for whom a tunneled catheter will be implanted. Surgery performed by a surgeon and resident Consent to participate in the study
Exclusion criteria:
History of coagulopathy Existence of high blood pressure at the same time as diabetes Presence of fatty liver and liver disease based on confirmation by liver enzyme test The presence of a disease that has contraindications for taking aspirin (such as nasal polyp disease, asthma, allergy to aspirin)

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **162**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned to three groups of Atorvastatin, Aspirin and Placebo based on the order of arrival and based on the randomization sequence that will be produced in advance. This sequence is unpredictable, and its arrangement is completely random. Block randomization method with 9 blocks will be used to allocate the samples. In this way, by using the block method random number generation software, the randomization sequence will be produced according to the required sample size for two groups. In the beginning, all the modes that can arrange 3 letters A, B and C in a block of 9 are produced. Then a block will be selected randomly and by placement among the blocks, and the arrangement pattern in that block will be used to allocate the participants. Then this block will be placed in

the main container and another block will be selected again. All these works will be done with a software called Sealed Envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. In this way, for atorvastatin and aspirin tablets, starch tablets similar to atrovastatin and aspirin will be prepared, which will be given to the opposite group and the placebo group. Therefore, each person in the study receives one pill from the supervisor, one of which is the drug in question and the other is a placebo, and in the placebo group, the person will take two placebo pills. For the second type of blinding, the drugs are prescribed by the relevant supervisor (principal guide) and are provided to the patients. The assistant of the relevant specialty does not know the type of prescription drugs of the patients and will only be responsible for collecting their clinical information through the checklist and file number.

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
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3848176941

Approval date
2023-08-29, 1402/06/07

Ethics committee reference number
IR.ARAKMU.REC.1402.134

Health conditions studied

1

Description of health condition studied
Dialysis

ICD-10 code
T80.21

ICD-10 code description
Infection due to central venous catheter

Primary outcomes

1

Description

Duration of catheter operation

Timepoint

The beginning of the intervention until 180 days later

Method of measurement

checklist

2

Description

Incidence of catheter infection

Timepoint

After the intervention

Method of measurement

checklist

3

Description

Occurrence of thrombosis

Timepoint

After the intervention

Method of measurement

Clinical examination and ultrasound

Secondary outcomes

1

Description

180 days operation

Timepoint

After the intervention

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group: Daily consumption of a 40 mg Atorvastatin tablet of Soban Daru company, along with a placebo aspirin tablet, from the day of catheter placement until 6 months or catheter removal.

Category

Treatment - Drugs

2

Description

Intervention group: Daily consumption of an 80 mg aspirin tablet by Galenus company along with a placebo tablet of atorvastatin from the day of catheter placement until 6 months or catheter withdrawal.

Category

Treatment - Drugs

3

Description

Control group: Daily consumption of two starch tablet as ordered by Soban Daru from the day of catheter placement until 6 months or catheter removal.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr hospital

Full name of responsible person

Dr. Reza Shojaei

Street address

Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mehdi Salehi

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Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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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

Dr. Reza Shojaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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

Arak University of Medical Sciences

Full name of responsible person

Dr. Elham Farahani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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

Arak University of Medical Sciences

Full name of responsible person

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Position

resident

Latest degree

Medical doctor

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General Surgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2024/07/20 to 2027/07/20 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

Academic researchers and university professors can request Dr. Reza Shojaei to use the data after contacting the relevant professor via message or email. Dr. Reza Shojaei: Phone: 09123700960 Email: R.shojaei@arak.mu.ac.ir Address: Valiasr Hospital, Arak, Vice-Chancellor of Hospital Education

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

Letter writing should be done with professors and universities.

Comments