Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

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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 atrostatin 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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