

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Assessment of the impact of Rivaroxaban in patients with peripheral artery disease (PAD) of the lower extremities who underwent endovascular revascularization to prevent major organ and cardiovascular side effects

Protocol summary

Study aim

Assessment of the impact of Rivaroxaban in patients with peripheral artery disease (PAD) of the lower extremities who underwent endovascular revascularization

Design

A controlled trial, parallel-group, single-blind, randomized; phase 4 clinical trial on 122 patients with a 6-month follow-up.

Settings and conduct

Medication intervention will be done in symptomatic patients with lower limb peripheral vessels who underwent endovascular revascularization surgery. The patients will be referred to Imam Ahvaz Hospital and the duration of the study is 6 months. Two intervention and control groups will receive medications for 6 months. Patients will be followed up one week, one month, three months and six months after starting the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Patients with peripheral artery disease (PAD) of the lower extremities who underwent endovascular revascularization; age above 50, Patients who have clinical need for systemic anticoagulation will not be included in the study.

Intervention groups

The intervention and control groups will receive medication. Patients in the intervention group will receive 2.5 mg Rivaroxaban tablet twice daily plus Aspirin once daily for 6 months, and the control group will receive 2.5 mg Plavix tablet twice a day plus Aspirin once a day for 6 months.

Main outcome variables

Status of wound, limb preservation, lameness, and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231117060086N1**

Registration date: **2023-11-26, 1402/09/05**

Registration timing: **prospective**

Last update: **2023-11-26, 1402/09/05**

Update count: **0**

Registration date

2023-11-26, 1402/09/05

Registrant information

Name

Arman Azmoon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3292 3985

Email address

dr.arman.azmoon2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the impact of Rivaroxaban in patients with peripheral artery disease (PAD) of the lower extremities who underwent endovascular revascularization to prevent major organ and cardiovascular side effects

Public title

Assessment of the impact of Rivaroxaban in peripheral artery disease (PAD) of the lower extremities

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with peripheral artery disease (PAD) of the lower extremities who underwent endovascular revascularization Age above 50 years

Exclusion criteria:

Clinical need for systemic anticoagulation

Age

From **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

To create a simple random sequence, two-group web-based randomization (www.graphpad.com) and to hide the random allocation, the method of packet envelopes with random sequence (SNOSE) will be used, several envelopes, preparation, and each of the sequences. The created coincidences are recorded on a card and the cards are placed in the letter envelopes in order. To preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed inside the boxes in order, at the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the letter envelopes is opened in order and the assigned group of that participant, it is revealed

Blinding (investigator's opinion)

Single blinded

Blinding description

It will be a single-blinded study. The researcher will be blinded about the type of medications, but the patients will be informed. To hide the drugs, they will be placed in a sealed, numbered envelope. The preparation of the envelopes will be done by a person, who will not be involved in the research.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan St. Jundishapur University of medical sciences

City

اهواز

Province

Khouzestan

Postal code

61357-15794

Approval date

2022-04-19, 1401/01/30

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.031

Health conditions studied

1

Description of health condition studied

Peripheral artery disease (PAD) of the lower extremities

ICD-10 code

I73.9

ICD-10 code description

Peripheral vascular disease, unspecified

Primary outcomes

1

Description

Status of Pain and lameness

Timepoint

Patients will be followed up for a visit one week, one month, three months and six months after starting the medication

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Status of heart attack, ischemic stroke, cardiovascular death, acute limb ischemia and limb amputation due to vascular causes

Timepoint

Patients will be followed up for a visit one week, one month, three months and six months after starting the intervention.

Method of measurement

Clinical examination

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

Intervention group; patients will receive 2.5 mg of Rivaroxaban tablet brand name (Axabin, Iran Hormon, Iran) twice a day plus 100 mg Aspirin tablet (A.S.A, Loghman Pharma, Iran) once a day for 6 months.

Category

Treatment - Drugs

2**Description**

Control group; patients will receive 2.5 mg Plavix tablet Brand name (Clopidogrel, Kobel Daru, Iran) twice a day plus 100 mg Aspirin (A.S.A, Loghman Pharma, Iran) once a day, for 6 months.

Category

Treatment - Drugs

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

Emam Hospital in Ahvaz

Full name of responsible person

Arman Azmoon

Street address

Azadegan St

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 7534

Email

dr.arman.azmoon2020@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Seyed Masoud Mousavi

Street address

Azadegan St, Ahvazian Ave, Emam Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 7534

Email

musavi-m@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Arman Azmoon

Position

Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Azadegan St, Ahvazian Ave, Emam Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3292 3985

Email

dr.arman.azmoon2020@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Arman Azmoon

Position

Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Azadegan St, Ahvazian Ave, Emam Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3292 3985

Email

dr.arman.azmoon2020@gmail.com

6135715794

Phone

+98 61 3292 3985

Email

dr.arman.azmoon2020@gmail.com

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

All data can be shared after anonymising the patients.

When the data will become available and for how long

Access period will start after publishing the results.

To whom data/document is available

Every body

Under which criteria data/document could be used

There is no barrier to access.

From where data/document is obtainable

Dr. Arman Amoon

Email:dr.arman.azmoon2020@gmail.com

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

Requesters can be informed of the final results by sending an email to the researcher and receiving a response within a week.

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

Ahvaz University of Medical Sciences

Full name of responsible person

Arman Azmoon

Position

Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Azadegan St, Ahvazian Ave, Emam Hospital

City

Ahvaz

Province

Khouzestan

Postal code