

# 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](http://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

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

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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**

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

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Surgeon

**Latest degree**

Specialist

**Other areas of specialty/work**

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