

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Studying the effect of Rivaroxaban 2.5 mg daily on Arteriovenous hemodialysis graft maintenance and thrombosis

Protocol summary

Study aim

Comparison of thrombus rate of artificial dialysis vessel in rivaroxaban receiving group and control group

Comparison of the average length of time the artificial dialysis vessel remained open in the group receiving rivaroxaban and the control group.

Design

A clinical trial with a control group with a simple blinded three-way parallel group on 78 patients for randomization from the site Randomization.com was used

Settings and conduct

Dialysis patients referred to the Vascular Surgery Department of Velayat Hospital who undergo artificial vein implantation for dialysis are randomly divided into two intervention and control groups.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Dependence on hemodialysis or the need for hemodialysis in the near future 2- Installing a new artificial vein for dialysis
Exclusion criteria: 1-Recent major bleeding (in the last 6 months) defined as follows: Bleeding requiring transfusion Bleeding in a high-risk area (retroperitoneal or intracranial), Bleeding that caused a decrease in body volume or hospitalization, or Bleeding that caused a Hg drop of more than 2 gr/dl. 2-Inability to eat oral medicine 3- Taking anticoagulant medicine for another reason 4- Survival of less than two months or waiting for recovery of kidney failure

Intervention groups

In the intervention group, after implanting an artificial dialysis vessel to the patient, 2.5 daily. mg of rivaroxaban is given for six months. In the control group, no anti-coagulant or anti-platelet drugs are given to the patient after the implantation of the artificial dialysis vessel.

Main outcome variables

Thrombosis rate of artificial vein in one, three and six months after implantation of artificial dialysis vessel

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231108059994N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **retrospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Ali Zangouei aval

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 814 9272

Email address

zangoueia4001@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

2023-03-21, 1402/01/01

Actual recruitment end date

2023-10-23, 1402/08/01

Trial completion date

2024-03-01, 1402/12/11

Scientific title

Studying the effect of Rivaroxaban 2.5 mg daily on Arteriovenous hemodialysis graft maintenance and thrombosis

Public title

Studying the effect of Rivaroxaban 2.5 mg daily on Arteriovenous hemodialysis graft maintenance and thrombosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Dependence on hemodialysis or the need for hemodialysis in the near future Installing a new artificial vein for dialysis

Exclusion criteria:

Recent major bleeding (within the last 6 months) that is defined as follows: bleeding requiring transfusion, bleeding in a high-risk area (retroperitoneal or intracranial), bleeding that caused a decrease in body volume or hospitalization, or bleeding that caused Hg drop is more than 2 gr/dl. Inability to take oral medication Anticoagulant use for another reason Life expectancy of less than two months or waiting for recovery of renal failure Open in

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

simple The envelope method is that the envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randaize.com and placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then, first, the purpose of the study is explained to the person who meets the stated conditions, and if the person wishes, he signs the informed consent form and takes an envelope, then opens it, and based on the contents of the envelope, the person is entered into the intervention or control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The envelope method is that the envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randaize.com and placed inside the envelope. The lid of the envelopes

will be closed and its contents will not be visible from the outside. Then, first, the purpose of the study is explained to the person who meets the stated conditions, and if the person wishes, he signs the informed consent form and takes an envelope, then opens it, and based on the contents of the envelope, the person is entered into the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad Medical Sciences

Street address

shahid kalantari Blvd. Mashhad University of Medical Sciences

City

mashhad

Province

Razavi Khorasan

Postal code

9137913131

Approval date

2023-06-15, 1402/03/25

Ethics committee reference number

IR.MUMS.IRH.REC.1402.079

Health conditions studied

1

Description of health condition studied

Artificial vein thrombosis in dialysis patients

ICD-10 code

T82.867A

ICD-10 code description

Thrombosis of cardiac prosthetic devices, implants and grafts, initial encounter

Primary outcomes

1

Description

Thrombosis rate of artificial vein in one, three and six months after implantation of artificial dialysis vessel

Timepoint

in one, three and six months after implantation of artificial dialysis vessel

Method of measurement

Occurrence of thrombosis in an artificial vessel

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after implanting an artificial dialysis vessel to the patient, 2.5 daily. mg rivaroxaban

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

velayat hospital

Full name of responsible person

Ali zangouei

Street address

shahid fakouri

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Postal code

9177899191

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Email

alila9071@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

mohsen tafaghodi

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Phone

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Jamal jalili shahri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular surgeon

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051387240

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Jamal jalili shahri

Position

asscciare professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular surgeon

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali zangouei aval

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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

No - There is not a plan to make this available