Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 failureOpen 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 Randomaize.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 Randomaize.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
City
mashhad
Province
Razavi Khorasan
Postal code
۹۱۷۷۸۹۰۰۰۱
Phone
+98 51 3872 2140
Email
aliila9071@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
mohsen tafaghodi
Street address
shahid kalantari Blvd
City
mashhad
Province
Razavi Khorasan
Postal code
9137913131
Phone
+98 51 3841 2081
Email
ZangoueiA4001@mums.ac.ir
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
Street address
velayat hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
051387240
Email
ZangoueiA4001@mums.ac.ir

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
Street address
Mashhad velayat hospital
City
Mashhad
Province
Razavi Khorasan
Postal code

9177899191

Phone

051387240

Email

ZangoueiA4001@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ali zangouei aval

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

velayat hospital

City

mashgad

Province

Razavi Khorasan

Postal code

9177899191

Phone

051387240

Email

ZangoueiA4001@mums.ac.ir

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