

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the Rivaroxaban 10mg on Tunneled cuffed catheter patency in hemodialysis patients

Protocol summary

Study aim

Comparison of thrombus rate of dialysis tunneled cuffed catheters in the group receiving rivaroxaban and the control group 2-Comparison of the average patency duration of cuffed tunneled dialysis catheters in the rivaroxaban receiving group and the control group.

Design

Dialysis patients referred to Mashhad province hospital who are candidates for implantation of cuffed tunneled catheter for hemodialysis are randomly assigned to intervention and control groups.

Settings and conduct

50 patients referred to the Vascular Surgery Department of Mashhad Province Hospital for the placement of a tunneled cuffed dialysis catheter during 1403 will be randomly assigned to two control and intervention groups. The analyst will be unaware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

All ESRD patients who are candidates for tunneled cuffed catheter implantation for dialysis.

Intervention groups

In the intervention group, 10 mg of rivaroxaban is given to the patient immediately after insertion of the cuffed catheter. In the control group, no medication is given to the patient after insertion of the dialysis cuffed catheter according to the standard protocol.

Main outcome variables

Incidence of intraluminal thrombosis in the first, third and sixth months after catheter insertion. The rate of catheter opening in the first, third and sixth months after catheter insertion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211026052874N1**

Registration date: **2025-01-11, 1403/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-11, 1403/10/22**

Update count: **0**

Registration date

2025-01-11, 1403/10/22

Registrant information

Name

Jamal Jalili Shahri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3804 7201

Email address

jalilisj@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-10, 1403/05/20

Expected recruitment end date

2025-02-09, 1403/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Rivaroxaban 10mg on Tunneled cuffed catheter patency in hemodialysis patients

Public title

Study of the Rivaroxaban 10mg on Tunneled cuffed catheter patency

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

ESRD patients who are candidates for Tunneled hemodialysis catheter placement as a permanent hemodialysis access

Exclusion criteria:

Presence of a coagulation disorder Two weight ranges (less than 50 kg and more than 150 kg) Receiving anticoagulant medication for another reason, such as cardiac DVT, atrial fibrillation, or an artificial heart valve Untreated malignant lesion of the central nervous system (CNS) Active lesion or active malignancy in the GI and GV system Platelet count less than 70,000

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to two intervention and control groups in order of arrival and based on a randomization sequence that will be generated in advance, which is an unpredictable sequence and its arrangement is completely random. A block randomization method with blocks of 8 will be used to allocate samples. Thus, using the site www.sealedenvelope.com, blocks of 8 letters A and B will be randomly generated based on the sample size. The order of the letters A and B in each block from the first block to the last block is considered as the randomization sequence. The generation of these blocks and their random sequence is entirely done by this site, and the researcher is not aware of their sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyst will be unaware of the intervention and control groups

Placebo

Not used

Assignment

Other

Other design features

The patients are divided into two research groups and control groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

4th Floor, Vascular Surgery Office, Velayat Hospital, Shahid Kaveh Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177890001

Approval date

2020-09-22, 1399/07/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.110

Health conditions studied

1

Description of health condition studied

Dysfunctional cuffed tunneled dialysis catheter

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Thrombosis of cuffed catheter with tunneled dialysis

Timepoint

one month and three months and six months

Method of measurement

Catheter patency rates in the first, third, and sixth months after catheter insertion and cases of catheter dysfunction due to intraluminal thrombosis in both intervention and control groups

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dialysis patients with a tunneled cuffed catheter are given one 10 mg rivaroxaban tablet daily. Patients are followed up at one, three, and six month intervals, and the number of catheter dysfunctions due to thrombosis is recorded.

Category

Treatment - Drugs

2

Description

Control group: After insertion of a cuffed dialysis catheter according to the current routine treatment process, no medication is given to the patient. Patients are followed up at one, three, and six month intervals and the number of cases of catheter dysfunction due to thrombosis is recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Dr Jamal Jalili Shahri

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Shahid Kaveh Blvd.,

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Web page address

<https://velayat.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.majid ghayour mobarhan

Street address

Shahid Kaveh Blvd., Velayat Hospital

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<https://velayat.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

Dr. Jamal Jalili Shahri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Jamal Jalili Shahri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular Surgery

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

Mashhad University of Medical Sciences

Full name of responsible person

Jamal Jalili Shahri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular Surgery

Street address

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City

Mashhad

Province

Razavi Khorasan

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

Undecided - It is not yet known if there will be a plan to make this available