# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

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+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 researcg 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

**Street address**
Shahid Kaveh Blvd.,

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Jalilisj@mums.ac.ir

**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

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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**
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

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**Position**
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## Person responsible for updating data

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**Other areas of specialty/work**
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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**
Undecided - It is not yet known if there will be a plan to make this available