

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Studying the Efficacy of Apixaban in the prevention of tunneled cuffed catheter (TCC) thrombosis in operated hemodialysis patients

#### Protocol summary

##### Study aim

Determining the efficacy of Apixaban in the prevention of tunneled cuffed catheter thrombosis in operated hemodialysis patients

##### Design

This study is a randomized controlled trial, without blinding, which will include 100 patients. The block randomization method will be used for randomization.

##### Settings and conduct

In Urmia Imam Khomeini Hospital, hemodialysis patients who will undergo TCC insertion will be selected. Patients will be randomly assigned to one of two intervention and control groups. The intervention group will receive oral apixaban at a dose of 2.5 mg daily for 6 months. The control group will undergo routine treatment in Iran. Apixaban for the intervention group will start one day after TCC insertion and will continue for up to 6 months. Any blockage, catheter infection, catheter replacement, and bleeding will be recorded in both groups.

##### Participants/Inclusion and exclusion criteria

Hemodialysis patients undergoing TCC procedures in Urmia Imam Khomeini Hospital will be included in the study. Patients treated with anticoagulant or other antiplatelet drugs, patients with life expectancy of less than 3 months, impaired coagulation tests (PTT-PT-INR) before intervention, known coagulation disorders, uncontrolled blood pressure, malignancy, pregnancy, breastfeeding, active infectious disease, liver failure, history of pulmonary embolism, or history of allergy to apixaban will not be included in the study.

##### Intervention groups

The intervention group will receive 2.5 mg apixaban pills everyday for 6 months. The control group will receive the conventional treatment in Iran.

##### Main outcome variables

catheter thrombosis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240228061124N1**

Registration date: **2024-10-18, 1403/07/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-10-18, 1403/07/27**

Update count: **0**

##### Registration date

2024-10-18, 1403/07/27

##### Registrant information

##### Name

Bahman Alinezhad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 9939

##### Email address

alinezhad.b@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-10, 1402/12/20

##### Expected recruitment end date

2025-03-19, 1403/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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| Studying the Efficacy of Apixaban in the prevention of tunneled cuffed catheter (TCC) thrombosis in operated hemodialysis patients |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Public title</b>                                                                                                                | Effect of Apixaban in catheter patency                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Purpose</b>                                                                                                                     | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Inclusion/Exclusion criteria</b>                                                                                                | <p><b>Inclusion criteria:</b><br/>Hemodialysis patients undergoing TCC insertion in Imam Khomeini Hospital of Urmia. being older than 18 years</p> <p><b>Exclusion criteria:</b><br/>Patients who are treated with anticoagulant or other antiplatelet drugs. Patients who have a life expectancy of less than 3 months. Patients who have abnormal coagulation tests (PTT-PT-INR) before starting the intervention. Patients with known coagulation disorders. Patients with uncontrolled hypertension. Patients who have malignancy. Patients who are pregnant. Patients who are breastfeeding. Patients with an active infectious disease. Patients with liver failure. Patients who have a history of allergy to apixaban. Patients with a history of pulmonary embolism.</p> |
| <b>Age</b>                                                                                                                         | From <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Gender</b>                                                                                                                      | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Phase</b>                                                                                                                       | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Groups that have been masked</b>                                                                                                | <i>No information</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Sample size</b>                                                                                                                 | Target sample size: <b>100</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Randomization (investigator's opinion)</b>                                                                                      | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Randomization description</b>                                                                                                   | In this study, two groups are to be randomized, with 50 participants receiving Apixaban and 50 participants not receiving it. Random Allocation Software Version 1.0 will be used for the random distribution, and block randomizing will be applied to guarantee equal distribution between the groups. Four participants will be the block size chosen by the Equal Size block option. Input into the program will be the overall sample size, the number of groups (Apixaban and non-Apixaban), and the block size.                                                                                                                                                                                                                                                            |
| <b>Blinding (investigator's opinion)</b>                                                                                           | Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Blinding description</b>                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Placebo</b>                                                                                                                     | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Assignment</b>                                                                                                                  | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Other design features</b>                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Secondary Ids</b>                                                                                                               | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

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|------------------------------------------------|------------------------------------------------------------------------------------------------------|
| <b>Ethics committees</b>                       |                                                                                                      |
| <b><u>1</u></b>                                |                                                                                                      |
| <b>Ethics committee</b>                        |                                                                                                      |
| <b>Name of ethics committee</b>                | Research Ethics Committees of Urmia University of Medical Sciences - Imam Khomeini University Hospit |
| <b>Street address</b>                          | Imam Khomeini University Hospital, Ershad Ave., Modarres Blvd.                                       |
| <b>City</b>                                    | Urmia                                                                                                |
| <b>Province</b>                                | West Azarbaijan                                                                                      |
| <b>Postal code</b>                             | 5715781351                                                                                           |
| <b>Approval date</b>                           | 2023-12-20, 1402/09/29                                                                               |
| <b>Ethics committee reference number</b>       | IR.UMSU.HIMAM.REC.1402.127                                                                           |
| <b>Health conditions studied</b>               |                                                                                                      |
| <b><u>1</u></b>                                |                                                                                                      |
| <b>Description of health condition studied</b> | End-stage renal disease                                                                              |
| <b>ICD-10 code</b>                             | N18.6                                                                                                |
| <b>ICD-10 code description</b>                 | End stage renal disease                                                                              |
| <b><u>2</u></b>                                |                                                                                                      |
| <b>Description of health condition studied</b> | Thrombosis-related malfunction of tunneled-cuffed central venous catheters (TCC)                     |
| <b>ICD-10 code</b>                             | T82.49                                                                                               |
| <b>ICD-10 code description</b>                 | Other complication of vascular dialysis catheter                                                     |
| <b>Primary outcomes</b>                        |                                                                                                      |
| <b><u>1</u></b>                                |                                                                                                      |
| <b>Description</b>                             | Thrombosis percentage of tunneled cuffed catheters                                                   |
| <b>Timepoint</b>                               | At the beginning of the study and then 6 and 12 months after the catheter was placed                 |
| <b>Method of measurement</b>                   | Observing the malfunction of the catheter in dialysis, bleeding and any related complications        |
| <b>Secondary outcomes</b>                      | empty                                                                                                |

## Intervention groups

### 1

#### Description

Intervention group: Patients will receive oral apixaban at a dose of 2.5 mg daily for 6 months.

#### Category

Prevention

### 2

#### Description

Control group: Patients will receive routine treatment in Iran. Patients do not routinely receive anticoagulants to prevent catheter thrombosis.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini University Hospital

##### Full name of responsible person

Bahman Alinezhad

##### Street address

Imam Khomeini University Hospital, Ershad Ave.,  
Modarres Blvd.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3346 9931

##### Fax

+98 44 3346 9935

##### Email

academic.relations@umsu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Saber Golizadeh

##### Street address

Deputy of research and technology, Urmia University  
of Medical Sciences, Jahad Ave.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3223 1930

##### Email

research@umsu.ac.ir

##### Web page address

<https://research.umsu.ac.ir/>

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Oroumia University of Medical Sciences

##### Proportion provided by this source

70

##### 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

Oroumia University of Medical Sciences

##### Full name of responsible person

Khodadad Ghaffari

##### Position

Medical student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

Imam Khomeini University Hospital, Ershad Ave.,  
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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Khodadad Ghaffari

##### Position

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Khodadad Ghaffari

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner