

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)

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+98 44 3346 9939

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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

Studying the Efficacy of Apixaban in the prevention of tunneled cuffed catheter (TCC) thrombosis in operated hemodialysis patients	
Public title	Effect of Apixaban in catheter patency
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: Hemodialysis patients undergoing TCC insertion in Imam Khomeini Hospital of Urmia. being older than 18 years Exclusion criteria: 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.
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	<i>No information</i>
Sample size	Target sample size: 100
Randomization (investigator's opinion)	Randomized
Randomization description	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.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Golizadeh

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Deputy of research and technology, Urmia University
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Web page address

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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

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

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Full name of responsible person

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Position

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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