Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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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
No information
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

1

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.
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Approval date
2023-12-20, 1402/09/29
Ethics committee reference number
IR.UMSU.HIMAM.REC.1402.127

Health conditions studied

1

Description of health condition studied
End-stage renal disease
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

2

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

1

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
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Sponsors / Funding sources

1

Sponsor
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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
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Position
Medical student
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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