Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of oral anticoagulants with injectable anticoagulants for prophylaxis of thrombosis in patients undergoing laparotomy surgery

Protocol summary

Study aim

compare the efficacy and safety of oral apixaban with subcutaneous enoxaparin for prevention of postoperative venous thromboembolism in women undergoing gynecologic oncology laparotomy.

Design

This is a randomized, controlled, parallel-group, open-label clinical trial with a 1:1 allocation ratio. Participants will be randomized individually using simple randomization through www.randomization.com. No blinding will be performed because the interventions have different routes of administration.

Settings and conduct

The trial will be conducted in the Gynecologic Oncology Department of Kowsar Hospital, Urmia. Eligible patients will be enrolled after written informed consent and randomly assigned to receive either oral apixaban or subcutaneous enoxaparin. Outcomes will be assessed during follow-up according to the study protocol.

Participants/Inclusion and exclusion criteria

Participants will be women aged 18 y/o or older with uterine, ovarian, or cervical cancer who undergo laparotomy and are able to follow a 28-day medication regimen. Patients must sign written informed consent. Patients with hypersensitivity to apixaban or enoxaparin, previous vascular events, previous long-term immobility or limb fracture, diseases predisposing to bleeding or thrombosis, or previous anticoagulant use before enrollment will not be included.

Intervention groups

Intervention group: Apixaban 2.5 mg oral tablet twice daily for 28 days after discharge. Control group: Enoxaparin 40 mg subcutaneous injection once daily for 28 days after discharge.

Main outcome variables

The main outcome is symptomatic venous thromboembolism, including deep vein thrombosis or pulmonary embolism, within 30 days after surgery. Secondary outcomes include bleeding events, medication adherence during the 28-day prophylaxis period, and patient costs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260209068807N1**
Registration date: **2026-05-18, 1405/02/28**
Registration timing: **prospective**

Last update: **2026-05-18, 1405/02/28**
Update count: **0**

Registration date

2026-05-18, 1405/02/28

Registrant information

Name

Arezou Divband

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4343 2441

Email address

dr.arezou.divband@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2027-04-20, 1406/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of oral anticoagulants with injectable anticoagulants for prophylaxis of thrombosis in patients undergoing laparotomy surgery

Public title
Effect of Oral Apixaban Compared with Injectable Enoxaparin in Preventing Blood Clots After Gynecologic Cancer Surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18 years or older. Women with uterine, ovarian, or cervical cancer undergoing laparotomy. Patients who are able to follow the 28-day medication regimen. Patients who sign the written informed consent form.

Exclusion criteria:
Known hypersensitivity to apixaban or enoxaparin. Previous history of vascular events. Previous long-term immobility or limb fracture. History of diseases predisposing to bleeding or thrombosis, such as antiphospholipid syndrome, hemophilia, or leukemia. Previous use of anticoagulant drugs before enrollment.

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to two study groups with a 1:1 allocation ratio. The unit of randomization is the individual participant. Simple randomization will be performed using the website www.randomization.com. No stratified randomization will be used. The random sequence will be generated before participant enrollment. Eligible participants will be assigned to either the apixaban group or the enoxaparin group according to the generated random sequence. Allocation concealment will be maintained by using coded group assignments until the time of allocation. For data analysis, the groups will be coded as Group X and Group Y to reduce analysis bias.

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
Urmia University of Medical Sciences (Research Ethics Committee)

Street address
Emergency Room, Urmia University of Medical Sciences, Resalat Boulevard, Urmia, West Azerbaijan Province, Iran

City
Urmia

Province
East Azarbaijan

Postal code
5716114819

Approval date
2026-01-28, 1404/11/08

Ethics committee reference number
IR.UMSU.REC.1404.461

Health conditions studied

1

Description of health condition studied
Venous thromboembolism

ICD-10 code
I82.9

ICD-10 code description
Embolism and thrombosis of unspecified vein

Primary outcomes

1

Description
Occurrence of symptomatic venous thromboembolism, including deep vein thrombosis or pulmonary embolism.

Timepoint
During follow-up up to 30 days after surgery.

Method of measurement
Clinical assessment and confirmation by color Doppler ultrasonography for suspected deep vein thrombosis and computed tomography scan for suspected pulmonary embolism.

Secondary outcomes

1

Description
Occurrence of bleeding events related to anticoagulant

drug use.

Timepoint

During follow-up up to 30 days after surgery.

Method of measurement

Clinical assessment and patient questionnaire.

2

Description

Medication adherence during the prophylaxis period.

Timepoint

During the 28-day prophylaxis period after discharge.

Method of measurement

Number of used doses divided by the total number of prescribed doses.

3

Description

Patient treatment costs.

Timepoint

At the end of the 28-day prophylaxis period after discharge.

Method of measurement

Patient questionnaire and recorded treatment costs.

Intervention groups

1

Description

Intervention group: Patients in this group will receive apixaban 2.5 mg oral tablet twice daily for 28 days after discharge.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Arezou Divband

Street address

Kosar Comprehensive Women's Educational and Medical Center, Hassani Street

City

Urmia

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West Azarbaijan

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5715859497

Phone

+98 914 635 2951

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kosar.hospital@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

Street address

Urmia University of Medical Sciences, Orzhans Alley, Resalat St. ,Urmia , Iran

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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

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

Oroumia University of Medical Sciences

Full name of responsible person

Arezou Divband

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Urmia, Hassani Street, Kosar Comprehensive Women's Educational and Medical Center

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified individual participant data related to the main study outcomes will be available upon reasonable request after publication of the final results. Shared data may include demographic variables, treatment group, occurrence of venous thromboembolism, bleeding events, medication adherence, and treatment costs. The study protocol, statistical analysis plan, informed consent form, clinical study report, and data dictionary will also be available upon reasonable request. Data will be shared only with researchers whose proposed use of the data is approved by the study investigators and, if required, by the relevant ethics committee. Data will be provided for scientific and non-commercial purposes only, after signing a data use agreement.

When the data will become available and for how long

The deidentified individual participant data and supporting documents will become available 6 months after publication of the final study results and will remain available for 5 years.

To whom data/document is available

The data and documents will be available to qualified researchers affiliated with academic, clinical, or research institutions for scientific and non-commercial purposes.

Under which criteria data/document could be used

Data and documents will be shared only after approval of a written research proposal by the study investigators. The proposed analysis should be scientifically valid and related to venous thromboembolism prophylaxis, bleeding events, medication adherence, treatment costs, or related clinical outcomes. The applicant must agree not to attempt to identify participants and not to share the data with third parties. A data use agreement must be signed before data transfer.

From where data/document is obtainable

Requests should be sent by email to the principal investigator, Dr. Arezou Divband, Urmia University of Medical Sciences. Email: divband.arezou@gmail.com. Requests should include the applicant’s affiliation, research proposal, planned analysis, and required documents or data.

What processes are involved for a request to access data/document

The applicant should submit a written request by email, including the research objective, requested data or documents, analysis plan, institutional affiliation, and ethics approval if required. The request will be reviewed by the study investigators within 4 weeks. If approved, the applicant will be asked to sign a data use agreement. After completion of the agreement, the approved deidentified data or documents will be provided within 2 to 4 weeks.

Comments

Shared data will be deidentified and will not include names, national identification numbers, phone numbers, addresses, or other direct identifiers.