Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of apixaban and enoxaparin on the prevention of postoperative vascular thromboembolism in women undergoing surgery for gynecological cancers

Protocol summary

Study aim

Comparison of the effect of apixaban and enoxaparin on the prevention of postoperative vascular thrombosis in women undergoing surgery for gynecological cancers

Design

Phase 3 clinical trial with a control group, parallel design, and randomized is performed on 200 patients.

Settings and conduct

This randomized study will be performed on 200 patients diagnosed with gynecological cancers who undergo laparotomy surgery in Imam Khomeini Hospital Complex. This is a single-blind study, the study outcome assessor does not know the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with gynecological cancers undergo laparotomy surgery. Criteria for not entering: Patients with the use of non-steroidal anti-inflammatory drugs, coagulation or bleeding disorders, severe kidney or liver diseases, valvular heart diseases, using thrombogenic drugs, selective serotonin reuptake inhibitors, or serotonin-norepinephrine reuptake inhibitors, history of venous thromboembolism.

Intervention groups

In the intervention group, enoxaparin (0.5 mg/kg) will be injected subcutaneously 12 hours before surgery, then 2.5 mg apixaban will be administered orally twice a day for 28 days. In the control group, enoxaparin (0.5 mg/kg) will be injected subcutaneously 12 hours before surgery, then enoxaparin (0.5 mg/kg) will be administered subcutaneously daily for 28 days.

Main outcome variables

The incidence of major bleeding or non-major bleeding with clinical significance till the first 30 days of after the surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141231020504N2**
Registration date: **2023-05-03, 1402/02/13**
Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**
Update count: **0**

Registration date

2023-05-03, 1402/02/13

Registrant information

Name
Arezoo Esmailzadeh
Name of organization / entity
Tehran University of Medical science
Country
Iran (Islamic Republic of)
Phone
+98 21 7788 3283
Email address
dr.a.esmailzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of apixaban and enoxaparin on the prevention of postoperative vascular thromboembolism in women undergoing surgery for gynecological cancers

Public title
Comparison of the effect of apixaban and enoxaparin on the prevention of postoperative vascular thromboembolism

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnosed with gynecological cancers (ovarian, uterine, cervical, or vulvar) undergo laparotomy surgery.

Exclusion criteria:
Long-term use of non-steroidal anti-inflammatory drugs Patients with coagulation or bleeding disorders, severe kidney or liver diseases, valvular heart diseases Using thrombogenic drugs, selective serotonin reuptake inhibitors, or serotonin-norepinephrine reuptake inhibitors History of venous thromboembolism

Age
From **18 years** old to **89 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method: Patients will be placed in two groups receiving apixaban group and enoxaparin group in a ratio of 1:1 using random blocks of four. In addition, interventions A (apixaban) or B (enoxaparin) are determined by a lot.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is performed single-blind, the study outcome assessor does not know the patient groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tehran Uviversity of Medical Science

Street address
Tehran University of Medical Sciences, Keshavarz blvd., Ghods st.

City
Tehran

Province
Tehran

Postal code
1598718311

Approval date
2021-08-04, 1400/05/13

Ethics committee reference number
IR.TUMS.IKHC.REC.1400.176

Health conditions studied

1

Description of health condition studied
Venous embolism and thrombosis

ICD-10 code
I82

ICD-10 code description
Other venous embolism and thrombosis

Primary outcomes

1

Description
Major bleeding incidence

Timepoint
Once, 30 days after the surgery

Method of measurement
Questioning

2

Description
Non-major bleeding incidence with clinical significance (requiring intervention)

Timepoint
Once, 30 days after the surgery

Method of measurement
Questioning

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, 12 hours

before surgery, 0.5 mg/kg enoxaparin (Iranhormone, Iran) will be injected subcutaneously, then 2.5 mg apixaban (Exir, Iran) will be administered orally twice a day for 28 days.

Category

Prevention

2

Description

Control group: In the control group, 12 hours before surgery, 0.5 mg/kg enoxaparin (Iranhormone, Iran) will be injected subcutaneously. Then, 0.5 mg/kg enoxaparin will be administered subcutaneously daily for 28 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Arezoo Esmailzadeh

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, Keshavarz Boulevard

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1419733141

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dr.a.esmailzadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotuohi

Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd

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1416634793

Phone

+98 21 8163 3689

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Arezoo Esmailzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Arezoo Esmailzadeh

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Esmailzadeh and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Esmailzadeh through email (dr.a.esmailzadeh@gmail.com)

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

Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Esmailzadeh.

Comments