

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the preventive effects of Apixaban and Enoxaparin on the postoperative vascular thromboembolism in patients undergoing surgery with gynecological and colorectal cancers

Protocol summary

Study aim

Comparison of the preventive effects of Apixaban and Enoxaparin on the postoperative vascular thromboembolism in patients undergoing surgery with gynecological and colorectal cancers

Design

Inclusion criteria: Patients diagnosed with gynecological and colorectal cancers undergo laparotomy surgery. Criteria for not entering: Patients with the use of non-steroidal anti-inflammatory drugs for more than one year, having other types of cancers, a history of thromboembolism, having severe kidney or liver diseases, having coagulation or bleeding disorders, using thrombogenic drugs, and pregnancy or breastfeeding.

Settings and conduct

In both groups, Heparin (5000 units, subcutaneous) is injected 30 minutes before skin incision. 18 to 24 hours after the termination of the operation, 0.5 mg/kg enoxaparin is injected subcutaneously and continues until discharge per day. After discharge for 28 days, in the intervention group, 2.5 mg of apixaban (Exir, Iran) will be administered orally twice a day and in the control group, 0.5 mg/kg enoxaparin will be administered subcutaneously.

Participants/Inclusion and exclusion criteria

Phase 3 clinical trial with a control group, parallel design, and randomized is performed on 160 patients.

Intervention groups

This randomized study will be performed on 160 patients diagnosed with gynecological and colorectal cancers who undergo laparotomy surgery in Baqiyatallah Hospital. This is a single-blind study, the study outcome assessor does not know the type of treatment.

Main outcome variables

The incidence of major bleeding or non-major bleeding with clinical significance till the first 90 days after the surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230419057967N1**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Farima Takizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 477 0768

Email address

farimatakizad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the preventive effects of Apixaban and Enoxaparin on the postoperative vascular thromboembolism in patients undergoing surgery with gynecological and colorectal cancers

Public title

Comparison of the preventive effects of Apixaban and Enoxaparin on the postoperative vascular thromboembolism

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with gynecological or colorectal cancers (rectum and colon) undergo laparotomy.

Exclusion criteria:

Use of non-steroidal anti-inflammatory drugs for more than one year Having other types of cancers History of thromboembolism Having severe kidney or liver diseases Having coagulation or bleeding disorders Using thrombogenic drugs Pregnancy or breastfeeding

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **160**

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

Ethics committee of Bagheiat-allah University of Medical Sciences

Street address

Bagheiat-allah Hospital, Mollasadra Street, Vanak Square.

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2023-09-30, 1402/07/08

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.064

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

The occurrence of major bleeding including hematoma and pelvic and abdominal bleeding

Timepoint

Three times, 30, 60 and 90 days after surgery

Method of measurement

Clinical symptoms and paraclinical findings

2

Description

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

Timepoint

Three times, 30, 60 and 90 days after surgery

Method of measurement

Clinical symptoms and paraclinical findings

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5000 units of Heparin (Caspianamin, Iran) are injected 30 minutes before skin incision, subcutaneously. 18 to 24 hours after the termination of the operation, 0.5 mg/kg enoxaparin (Iran Hormone,

Iran) is injected subcutaneously and continues until discharge per day. After discharge for 28 days, 2.5 mg of apixaban (Exir, Iran) will be administered orally twice a day.

Category

Prevention

2**Description**

Control group: 5000 units of Heparin (Caspianamin, Iran) are injected 30 minutes before skin incision, subcutaneously. 18 to 24 hours after the termination of the operation, 0.5 mg/kg enoxaparin (Iran Hormone, Iran) is injected subcutaneously and continues until discharge per day. After discharge for 28 days, 0.5 mg/kg enoxaparin will be administered subcutaneously daily for 28 days.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bagheiat-allah Hospital

Full name of responsible person

Farima Takizad

Street address

Bagheiat-allah Hospital, Mullasadra Street, Vanak Square.

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0436

Email

farimatakizad@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Bagheiat-allah University of Medical Sciences, Dr. Saberi

Street address

Vice-Dean of Research, Bagheiat-allah Hospital, Mullasadra Street, Vanak Square.

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8126 7457

Email

msaberi@bmsu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Farima Takizad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Fax**Email**

farimatakizad@yahoo.com

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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.Takizad and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Takizad through email (farimatakizad@yahoo.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. Takizad.

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Farima Takizad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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