Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the Efficacy and Safety of Rivaroxaban Versus Enoxaprin (Low-Molecular-Weight Heparin) As Post-surgical Thromboprohylaxis of Colorectal Cancer: A Randomized Clinical Trial

Protocol summary

Study aim

To determine the efficacy and safety of rivaroxaban as thromboprophylaxis after colorectal cancer surgery compared to LMWH

Design

The intervention group will receive oral rivaroxaban for 28 days, while the control group will receive subcutaneous enoxaparin for 28 days. Patients will be allocated in parallel at a 1:1 ratio, with 55 patients randomly assigned to each group.

Settings and conduct

This study will be conducted on patients with colorectal cancer who undergo surgery in the Colorectal Surgery Department of Imam Khomeini Hospital, Tehran, in 2026. Randomization will be performed using a computer-generated random list, in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion: Age over 18 years; candidate for colorectal cancer surgery; pathological confirmation of colorectal adenocarcinoma; patient consent; hospitalization for 6 to 7 days following surgery; creatinine clearance ≥30 mL/min; ALT/AST <3 times the upper limit of normal
Exclusion: Active bleeding; high risk of bleeding with anticoagulant use; concurrent use of anticoagulants (particularly warfarin and apixaban); use of dabigatran or edoxaban; history of heparin-induced thrombocytopenia; icreatinine clearance <30 mL/min; Child-Pugh Class C; pregnancy or lactation; platelet count <50,000/µL; major bleeding within the past 30 days; emergency surgery; metastatic disease with a life expectancy of less than three months; history of thromboembolism within the past 3 months

Intervention groups

Patients in this group will receive Rivaroxaban 10 mg orally, once daily, starting 6-10 hours after surgery. The duration of treatment will be 28 days. Rₒvaroxaban group= 55 patients

Main outcome variables

Venous thromboembolism, including DVT or PE, asymptomatic DVT detected by ultrasound, or VTE-related death within 90 days after surgery. Major bleeding, clinically relevant non-major bleeding, treatment adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260522069491N1**
Registration date: **2026-07-15, 1405/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-15, 1405/04/24**
Update count: **0**

Registration date

2026-07-15, 1405/04/24

Registrant information

Name

Aysa Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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aysa.rezaei80@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-01, 1405/04/10

Expected recruitment end date

2027-07-01, 1406/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy and Safety of Rivaroxaban Versus Enoxaprin (Low-Molecular-Weight Heparin) As Post-surgical Thromboprohylaxis of Colorectal Cancer: A Randomized Clinical Trial

Public title

Is Rivaroxaban safe and how does it work for Preventing Blood Clots After Colon Cancer Surgery, Compared to Enoxaparin?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Candidate for colorectal cancer surgery Pathological confirmation of colorectal adenocarcinoma Patient consent Hospitalization for 6 to 7 days following surgery Adequate renal function (creatinine clearance ≥30 mL/min) Adequate hepatic function (ALT/AST <3 times the upper limit of normal)

Exclusion criteria:

Active bleeding High risk of bleeding with anticoagulant use Concurrent use of anticoagulants (particularly warfarin and apixaban) Use of strong CYP3A4 inducers (e.g., rifampin, rifabutin, carbamazepine, phenytoin, phenobarbital, or St. John's Wort [Hypericum perforatum]) Use of dabigatran or edoxaban Use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, posaconazole, erythromycin, indinavir, saquinavir, Verapamil, diltiazem, amiodarone, quinidine) Use of mifepristone or urokinase History of heparin-induced thrombocytopenia Inadequate renal function (creatinine clearance <30 mL/min) Inadequate hepatic function (Child-Pugh Class C) Pregnancy or lactation Platelet count <50,000/µL Major bleeding within the past 30 days Emergency surgery Metastatic disease with a life expectancy of less than three months History of thromboembolism within the past 3 months

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Sequentially numbered, opaque, sealed envelopes will be used. These envelopes will be prepared by an individual with no executive or clinical role in the study, and the codes on them will correspond to the master randomization list. Only after final confirmation of eligibility criteria and obtainment of written informed consent will the envelope corresponding to the patient be opened in numerical sequence. This process completely prevents selection bias at the stage of study enrollment. The study will be conducted in a double-blind manner. Given the difference in the physical nature of the medications (tablet versus prefilled syringe), all medications and injection supplies will be placed in kit-like packaging (Study Kits) with completely identical appearance, weight, and dimensions. Each medication kit will bear only a unique identification code. Patients, nursing staff, treating physicians, and even outcome assessors (Doppler ultrasound specialists) will remain blinded to the contents of the kits until the completion of the data analysis phase. The master code list will be held exclusively by the Principal Investigator in an encrypted file. Unblinding will be performed only in medical emergencies where knowledge of the drug type is essential to save the patient's life, in accordance with the approved protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Vice Chancellor for Research and Technology, Tehran University of Medical

Street address

Keshavarz Boulevard, corner of Qods Street, Central Administration Building, Tehran University of Medical Sciences, 6th Floor, Rooms 604–605

City

Tehran

Province

Tehran

Postal code

141765383761

Approval date

2026-05-19, 1405/02/29

Ethics committee reference number

IR.TUMS.IKHC.REC.1405.074

Health conditions studied

1

Description of health condition studied
Ascending colon cancer
ICD-10 code
C18.2
ICD-10 code description
Malignant neoplasm of ascending colon

2

Description of health condition studied
transverse colon cancer
ICD-10 code
C18.4
ICD-10 code description
Malignant neoplasm of transverse colon

3

Description of health condition studied
descending colon cancer
ICD-10 code
C18.6
ICD-10 code description
Malignant neoplasm of descending colon

4

Description of health condition studied
sigmoid colon cancer
ICD-10 code
C18.7
ICD-10 code description
Malignant neoplasm of sigmoid colon

5

Description of health condition studied
rectum cancer
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

6

Description of health condition studied
deep vein thrombosis
ICD-10 code
I82.4
ICD-10 code description
Acute embolism and thrombosis of deep veins of lower extremity

7

Description of health condition studied
pulmonary embolism
ICD-10 code
I26
ICD-10 code description
Pulmonary embolism

Primary outcomes

1

Description
Symptomatic venous thromboembolism (VTE)
Timepoint
Development of symptoms including severe dyspnea or unilateral lower extremity swelling up to 90 days after surgery
Method of measurement
Clinical and imaging diagnosis

2

Description
A symptomatic venous thromboembolism (VTE)
Timepoint
Final day of hospitalization, day 30, and day 90 after surgery
Method of measurement
Venous Doppler ultrasound

3

Description
Death resulting from venous thromboembolism (VTE)
Timepoint
Death within 90 days after surgery due to venous thromboembolism (VTE)
Method of measurement
Medical record, death report

4

Description
Major bleeding
Timepoint
Within 90 days after surgery
Method of measurement
Clinical report, medical record

5

Description
Clinically relevant non-major bleeding
Timepoint
Within 90 days after surgery
Method of measurement
Clinical report, medical record

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fifty-five patients in this group will receive one 10-mg tablet of rivaroxaban (Actoverco) once daily for 28 days as postoperative thromboprophylaxis following colorectal cancer surgery at Imam Khomeini Hospital, Tehran. During hospitalization, rivaroxaban will be prescribed through the hospital ward's medication order system. Upon discharge, patients will be instructed on the proper administration of the medication. In addition, each patient will be provided with a sufficient number of rivaroxaban tablets to complete the 28-day treatment course.

Category

Treatment - Drugs

2

Description

Control group: Fifty-five patients in this group will receive one 40-mg subcutaneous injection of enoxaparin sodium (Exir Pharmaceutical Company) once daily for 28 days as postoperative thromboprophylaxis following colorectal cancer surgery at Imam Khomeini Hospital, Tehran. During hospitalization, the medication will be prescribed through the hospital ward's medication order system. Upon discharge, patients will receive instructions on the proper administration of the medication. In addition, each patient will be provided with a sufficient supply of enoxaparin sodium to complete the 28-day treatment course.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdi Clinic, Imam Khomeini Hospital Complex

Full name of responsible person

Mohsen Ahmadi Tafti

Street address

Tehran, end of Keshavarz Boulevard, Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 5462

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ms. Tahereh Hemmati

Street address

School of Medicine, Tehran University of Medical Sciences, Pour Sina Street, Qods Street, Enghelab Avenue, Tehran, Iran.

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deanmed@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

Aysa Rezaei

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Tehran University of Medical Sciences, Poursina Street, Qods Street, Enghelab Street, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohsen Ahmadi Tafti
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Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Tehran, end of Keshavarz Boulevard, Imam Khomeini Hospital Complex, Mahdi Clinic, Colorectal surgery department
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Aysa Rezaei
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Medical student
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A Level or less
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1461884513
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+98 21 8896 1697
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aysa.rezaei80@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Patient data, including age, sex, body mass index (BMI), cancer stage, type of surgery, and history of previous venous thromboembolism (VTE), will be recorded without including any patient identifiers in the final report. The study protocol will document the methodology of randomization, the study period, the patient follow-up procedures, and the patient selection criteria. A blank copy of the informed consent form will be included in the study documentation, and the completed informed consent forms of all participants will be securely retained. Upon completion of the study, statistical analyses will be performed on the collected variables, and the results will be presented in the final report
When the data will become available and for how long
Access to the study data will begin three months after publication of the study results.
To whom data/document is available
Data access will be granted only to researchers affiliated with accredited academic and scientific institutions.
Under which criteria data/document could be used
The data may be used for conducting related research, including literature reviews, systematic reviews, and meta-analyses.
From where data/document is obtainable
via email to: aysa.rezaei80@gmail.com or jamil.nadimi@gmail.com
What processes are involved for a request to access data/document
To obtain access to the data, applicants will be required to provide their full name, academic affiliation and position, and a summary of their research background. They must also submit a description of the purpose of the data request, the proposed research plan, and the anticipated timeline and method for dissemination of the study findings.
Comments