# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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. R₀varoxaban 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**
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Iran (Islamic Republic of)
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**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

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Tehran

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**Postal code**

1419733141

**Phone**

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**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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**Province**

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+98 21 8896 1697

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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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aysa.rezaei80@gmail.com

## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**
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**Position**
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**Latest degree**
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**Other areas of specialty/work**
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Tehran, end of Keshavarz Boulevard, Imam Khomeini Hospital Complex, Mahdi Clinic, Colorectal surgery department
**City**
Tehran
**Province**
Tehran
**Postal code**
1419733141
**Phone**
+98 21 6119 5462
**Email**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Position**
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**Street address**
School of Medicine, Tehran University of Medical Sciences, Poursina Street, Qods Street, Enghelab Street, Tehran, Iran
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1461884513
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**Email**
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**