

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of oral anticoagulants (Rivaroxaban and Apixaban) and injectable drugs (Heparin and Enoxaparin) to prevent bleeding in patients undergoing oncological gynecological surgeries

Protocol summary

Study aim

Comparison of the effects of oral (rivaroxaban and apixaban) and injectable (heparin and enoxaparin) anticoagulant drugs in patients undergoing gynecological oncological surgeries

Design

This study is a open label clinical trial, with two parallel groups, randomized, phase 2 on 80 patients, which is conducted in two groups of 40 people receiving oral and injectable anticoagulants. The method of randomization is based on the table of random numbers.

Settings and conduct

This study is a open label clinical trial, with two parallel groups, randomized, phase 2 on 80 patients, which is conducted in two groups of 40 patients receiving oral and injectable anticoagulants on patients referred to Firouzgar Hospital in Tehran. The method of randomization is based on the table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 to 70 years Obtain informed consent Having cancer complications Exclusion Criteria: Liver and kidney failure (glomerular filtration rate (GFR) less than 30) Deep vein thrombosis (DVT) and Post-transplant erythrocytosis (PTE) History of GI Pregnancy and breast feeding Using anticoagulants

Intervention groups

All patients are treated with injectable anticoagulants (heparin and enoxaparin) before surgery and during hospitalization. After discharge from the hospital, patients are randomly divided into two groups of 40 people (the group receiving oral anticoagulants, apixaban and rivaroxaban=40 people with a dose of 2.5 mg twice a day after surgery and the group receiving injectable anticoagulants=40 people with a dose of 5,000 units once a day after surgery) and within 28 days they use two defined medical treatment protocols.

Main outcome variables

Bleeding in the organs, disorder in the size, shortness of breath, pain in the organs, swelling in the organs, chest pain, time of drug administration and Doppler ultrasound results of the organs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053991N1**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

amineh arab khazael mahabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7711 8432

Email address

amym.940225@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-09, 1402/03/19

Expected recruitment end date

2023-09-10, 1402/06/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of oral anticoagulants (Rivaroxaban and Apixaban) and injectable drugs (Heparin and Enoxaparin) to prevent bleeding in patients undergoing oncological gynecological surgeries

Public title
Comparison of the effects of Rivaroxaban and Apixaban with Heparin and Enoxaparin in patients undergoing gynecological oncological surgery.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 70 years Obtaining informed consent Cancer disease
Exclusion criteria:
Liver failure Deep vein thrombosis (DVT) History of Gastrontestinal bleeding Pregnancy Taking other anticoagulants Breast feeding Post-transplant erythrocytosis (PTE) PTE disorders Kidney failure (glomerular filtration rate (GFR) less than 30)

Age
From **18 years** old to **70 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Referral patients are randomly divided into two groups receiving oral and injectable anticoagulation drugs. Random number table is used for randomization. Odd numbers for the oral anticoagulation group and even numbers for the injectable drug group.

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
Ethics committee of Iran University of Medical Sciences
Street address
Hemmat highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۶۱۴۵۳۵

Approval date
2021-07-08, 1400/04/17

Ethics committee reference number
IR.IUMS.FMD.REC.1400.190

Health conditions studied

1

Description of health condition studied
Women's cancers including: endometrium, ovary, cervix, vulva

ICD-10 code
C55

ICD-10 code description
Malignant neoplasm of uterus, part unspecified

Primary outcomes

1

Description
Shortness of breath

Timepoint
Before and after surgery

Method of measurement
Examination

Secondary outcomes

1

Description
Bleeding

Timepoint
Before and after surgery

Method of measurement
Examination

2

Description
Pain

Timepoint
Before and after surgery

Method of measurement
Examination

3

Description

Size of organ

Timepoint

Before and after surgery

Method of measurement

Examination

4

Description

Time to take the medicine

Timepoint

Before and after surgery

Method of measurement

Questionnaire

5

Description

Doppler ultrasound results

Timepoint

Before and after surgery

Method of measurement

ultrasound

6

Description

Swelling of the limbs

Timepoint

Before and after surgery

Method of measurement

Examination

Intervention groups

1

Description

The first intervention group: the group receiving oral anticoagulant tablets apixaban and rivaroxaban with a dose of 2/5 mg twice a day after surgery, for 28 days, manufactured by Aburihan Pharmaceutical Company of Iran.

Category

Treatment - Drugs

2

Description

Intervention group: The group receiving anticoagulation injection drugs (heparin and enoxaparin), with a dose of 5,000 units once a day after surgery, for 28 days, manufactured by Aburihan Pharmaceutical Company of Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

Amine Arab

Street address

Vali asr SQ, Beafarij Av

City

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Province

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Phone

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Email

h_firoozgar@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Hossein Kiwani

Street address

Hemat Highway, Iran University of Medical Sciences

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+98 21 8670 2504

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keyvani.h@iums.ac.ir

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Amine Arab

Position

STUDENT

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Hemat Highway, Iran University of Medical Sciences

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Student

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient information is confidential according to the ethical work protocol

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only the results of the article are published, keeping the confidentiality of the patients' information.

When the data will become available and for how long

A month after the publication of the article

To whom data/document is available

University researchers

Under which criteria data/document could be used

Therapeutic use of the results of this study.

From where data/document is obtainable

Supervisor

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

Refer to supervisor keyvani.h@iums.ac.ir

Comments