

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effects of oral and injectable antiquaguane in the prevention of thromboembolic events in patients with gynecological cancers who underwent surgery.

Protocol summary

Registration timing: **prospective**

Study aim

Determining and comparing the effects of oral and injectable anticoagulants in the prevention of thromboembolic events in patients with gynecological cancers who underwent surgery.

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 2 on 100 patients. A table of random numbers was used for randomization.

Registrant information

Name

Seyede zahra Anaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3833 0206

Email address

mjp_368@yahoo.com

Settings and conduct

This study is conducted on women who had a history of surgery for gynecological cancers and are candidates for receiving oral or injectable anti coagulants. This study will be conducted in 2023 in Al-Zahra Hospital and Beheshti Hospital in Isfahan. Blinding was not done in this study.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

This study is conducted on women who have a history of surgery for gynecological cancers and are candidates for receiving oral or injectable anticoagulants. People with a history of thromboembolic events will not be included in the study

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

The intervention performed in this study is the administration of oral anticoagulant drug (Apixaban) in one group and the administration of injectable anticoagulant (Enoxaparin) in the other group.

Main outcome variables

Thrombosis

Scientific title

Comparison of the effects of oral and injectable antiquaguane in the prevention of thromboembolic events in patients with gynecological cancers who underwent surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231026059867N1**

Registration date: **2023-11-08, 1402/08/17**

Public title

Oral and injectable anti-thrombotic in the prevention of thromboembolic events

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People who have undergone surgery for gynecological cancers Candidate to receive oral or injectable anticoagulants

Exclusion criteria:

Lack of consent to continue participating in the study
History of thromboembolic events

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is simple and done with the help of a table of random numbers. According to the number of participants in the study, a sequence of random numbers is created with the help of a random number table, and each number is placed in an aluminum envelope, and the back of the envelopes is numbered according to the sequence process. According to the order of entry into the study, an envelope is opened and the sequence number inside is determined. If the number is even, the person will be placed in the second group, and if the number is odd, the person will be placed in the first 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 Isfahan University of Medical Sciences

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-05-23, 1402/03/02

Ethics committee reference number

IR.MUI.MED.REC.1402.091

Health conditions studied

1

Description of health condition studied

Thrombosis

ICD-10 code

I82.4

ICD-10 code description

Acute embolism and thrombosis of deep veins of lower extremity

2

Description of health condition studied

Pulmonary embolism

ICD-10 code

I26

ICD-10 code description

Pulmonary embolism

Primary outcomes

1

Description

Venous thrombosis

Timepoint

2 and 6 and 12 weeks after starting treatment

Method of measurement

Physical examination and history taking

2

Description

Pulmonary embolism

Timepoint

2 and 6 and 12 weeks after starting treatment

Method of measurement

Physical examination and history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving the oral anticoagulant apixaban tablets made in Elixir Pharmaceutical Company, 2.5 mg twice a day for 3 months.

Category

Treatment - Drugs

2**Description**

Intervention group: Received the subcutaneous anticoagulant enoxaparin ampoule manufactured in Octorco pharmaceutical company, 40 mg once a day for 3 months.

Category

Treatment - Drugs

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

Al zahra hospital

Full name of responsible person

Zahra Anaie

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

mjp_368@yahoo.com

2**Recruitment center****Name of recruitment center**

Beheshti hospital

Full name of responsible person

Zahra Anaie

Street address

Beheshti street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

mjp_368@yahoo.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Anaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

mjp_368@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Anaie
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mjp_368@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Anaie
Position
Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Hezar Jarib

City

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Province

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Postal code

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Phone

+98 31 3668 0048

Email

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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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available