

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of safety and efficacy of PDxane® in comparison to Clexane® in prophylaxis of venous thromboembolism in Major Gynecology Surgeries

Protocol summary

Study aim

Evaluation of safety and efficacy of PDxane® vs Clexane® in prophylaxis of venous thromboembolism in Major Gynecology Surgeries

Design

Single Blind randomized clinical trial, interventional groups with 100 patients, randomization with Randomization block method.

Settings and conduct

This study will be performed in Gynecology ward of Dr.Shariati Hospital, Tehran, Iran since March 2016. According to the Latest National Guideline of Gynecology surgeries, the subcutaneous dose of 40 mg enoxaparin every 24 hours for patient with less than 90 kilograms and 60 mg enoxaparin every 24 hours will be prescribed for indication of thromboprophylaxis. The initial dose of anticoagulant for each patient will be administrated at the hospital and rests of medications will be injected by the patients after discharge. All the patients individually would be educated about the impact of anticoagulants in their treatment process, self-injection of subcutaneous anticoagulant and how to manage the probable side effects of medications.

Participants/Inclusion and exclusion criteria

In: Adult (aged 18+) Major Gynecology Surgeries Ex : Having clinical symptoms of thrombosis having active hemorrhage or a high risk of bleeding History of thromboembolic diseases Malignancy Severe renal impairment Significant liver disease Treatment with warfarin Pregnancy

Intervention groups

intervention : PDxane® 40 mg SC if <90 kg and 60 mg if > 90 kg for 10 days, control: Clexane® 40 mg SC if <90 kg and 60 mg if > 90 kg for 10 days

Main outcome variables

1- Evaluation of effectiveness ,Prevention of thrombosis and/or Pulmonary Thromboembolism, Changes in the

active component of thromboplastin (APTT) and Thrombin clotting time (TCT) 2- Evaluation of unwanted side effects ,Postoperative bleeding, Hematoma in the surgical site, Infections in the surgical site, Itching and allergy to the drug, Hematoma in injection site)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090914002459N2**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **retrospective**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

84902364

Email address

mrjavadi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-02-19, 1394/11/30

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of safety and efficacy of PDxane® in comparison to Clexane® in prophylaxis of venous thromboembolism in Major Gynecology Surgeries

Public title
Evaluation of safety and efficacy of PDxane® in comparison to Clexane® in prophylaxis of venous thromboembolism in Major Gynecology Surgeries

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Major Gynecology Surgeries Adult (aged 18 and more)
Exclusion criteria:
Having clinical symptoms of Venous thrombosis Having active bleeding or a high risk of bleeding History of thromboembolic diseases Malignancy Pregnancy Severe renal impairment Significant liver disease

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
The primary investigator, researcher who perform outcome assessment and the analyst are not aware of allocations. A randomized list would be provided to pharmacy personnel and he will allocate patients based on the list and deliver the appropriate medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Tehran University of Medical Sciences

Street address

Jalal ale ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2016-02-14, 1394/11/25

Ethics committee reference number

IR.TUMS.REC.1394.1956

Health conditions studied

1

Description of health condition studied

Venous Thromboembolism following major gynecology surgery

ICD-10 code

I74.9

ICD-10 code description

Embolism and thrombosis of unspecified artery

Primary outcomes

1

Description

prevention of Venous Thromboembolism

Timepoint

10 days after surgery

Method of measurement

History taking and clinical assessments

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : Receiving an enoxaparin drug with the PDxane® brand to test the effects of thrombophilaxy and side effects.

Category

Prevention

2

Description

Intervention group2: Receiving an enoxaparin drug with the Clexane® brand to test the effects of thrombophilaxy and side effects.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mohammadreza Javadi

Street address

Jalal ale ahmad Highway

City

Tehran

Province

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Postal code

1411713135

Phone

+98 21 0218 4901

Email

shariatihosp@tums.ac.ir

Web page address

http://shariati.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pooyesh Darou Pharmaceuticals Co.

Full name of responsible person

Sina Ebrahimi

Street address

No466, Vali e asr Ave.Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8894 7910

Email

info@pooyeshdarou.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pooyesh Darou Pharmaceuticals Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Javadi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Dr.Shariatie Hospital, Jala ale ahmad Highway,

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Considering potential conflicts in this study in which the efficacy and safety of two brands of a medication are compared, dissemination of original data set would not be feasible.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Not applicable