

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of enoxaparin and aspirin in the prevention of deep venous thrombosis in patients undergoing orthostatic surgery for the reconstruction of anterior cruciate ligament

Protocol summary

Study aim

Comparison of the efficacy of enoxaparin and aspirin in the prevention of deep venous thrombosis in patients undergoing orthostatic surgery for the reconstruction of anterior cruciate ligament

Design

Clinical trials were randomized, double blind, with parallel groups and a sample size of 120 patients

Settings and conduct

120 patients will be randomly assigned to either the aspirin or the enoxaparin group according to the criteria for entering and leaving the study. In the enoxaparin group, treatment with enoxaparin 40 mg daily and subcutaneously for 10 days and the aspirin group will receive aspirin 325 mg twice daily for 20 days.

Researchers, and the person analyzing the data are not aware of the type of drug received and the grouping.

Participants/Inclusion and exclusion criteria

Entry conditions: Candidate for surgical reconstruction of anterior cruciate ligament Age between 19 and 55 Non-entry condition: Weight above 100 kg

Intervention groups

120 patients will be randomly assigned to either the aspirin or the enoxaparin group according to the criteria for entering and leaving the study. In the enoxaparin group, treatment with enoxaparin 40 mg daily and subcutaneously for 10 days and the aspirin group will receive aspirin 325 mg twice daily for 20 days.

Main outcome variables

Deep vein thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N7**

Registration date: **2019-07-27, 1398/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-27, 1398/05/05**

Update count: **0**

Registration date

2019-07-27, 1398/05/05

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2019-08-01, 1398/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of enoxaparin and aspirin in the prevention of deep venous thrombosis in patients undergoing orthostatic surgery for the reconstruction of anterior cruciate ligament

Public title

Prevention of DVT in ACL

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate for surgical reconstruction of anterior cruciate ligament Age from 19 to 55 years

Exclusion criteria:

Weight greater than 100 kg

Age

From **19 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be placed on a random number table and each person will be given a number from zero to 120. Coupled numbers will be in the aspirin group and the individual numbers will be in the enoxaparin group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list of patients will be given to the caregiver and the caregiver will implement the type of intervention. The results of each person will only be recorded by the carer, and the data analyzer and the investigator will be unaware of the type of intervention received for each patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2019-06-17, 1398/03/27

Ethics committee reference number

IR.TBZMED.REC.1398.307

Health conditions studied**1****Description of health condition studied**

Deep vein thrombosis

ICD-10 code

I80.2

ICD-10 code description

Phlebitis and thrombophlebitis of other and unspecified deep vessels of lower extremities

Primary outcomes**1****Description**

Deep vein thrombosis

Timepoint

Daily

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Treatment with enoxaparin with a dose of 40 mg will be given daily and subcutaneously for 10 days.

Category

Prevention

2**Description**

Control group: Treatment with aspirin 325 mg twice daily for 20 days will be performed.

Category

Prevention

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

Imam Reza Hospital

Full name of responsible person

Amir Mohammad Navali

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

6165665631

Phone

+98 41 3335 5921

Email

Drvaez@yahoo.com

Position

Resident of orthopedics

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764873

Phone

+98 41 3334 7054

Fax**Email**

Drvaez@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Ajouyban@hotmail.com

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

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Mousavi Vaezi

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Mousavi Vaezi

Position

Resident of orthopedics

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Drvaez@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax**Email**

Khanbabayimehdi69@gmail.com

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

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

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