

# 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

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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

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jouyban

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Imam Reza Hospital, Azadi Ave

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**Phone**

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**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

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**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

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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**

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