

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of Aspirin with Enoxaparin Sodium for prevention of deep vein thrombosis in Tibial fractures

#### Protocol summary

##### Study aim

Aspirin efficacy for prevention of deep vein thrombosis in tibial shaft fractures

##### Design

A double-blinded study, computer-based randomized, two-arm parallel-group, phase two clinical trial that involves 460 patients. Patients use medication for 35 days after discharge and follow for 6 months.

##### Settings and conduct

Patients referred to Sina hospital with Tibial fracture; patients are divided into two groups. The first group undergoes Aspirin 325 mg BD, the second group undergoes Enoxaparin 30 mg. In the time of hospitalization, all patients see serial examinations to evaluate DVT. If clinical manifestations of DVT are observed, Doppler ultrasonography will preform. Patients will follow for six months, in the first week, the first month, the third month, and the sixth month after discharge, we will arrange meetings. Patients will be advised to refer to Sina hospital if clinical manifestations of DVT occur. Patients will only enter the study with their consent and wouldn't notice the exact type of their anti-coagulant. This study is double-blinded.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: 1. male and female patients between 14 to 85 years old; 2. Tibial fracture with or without surgery indication. exclusion criteria: 1. hip or femur fracture; 2. major fracture except for tibia; 3. DVT or PTE history; 4. low platelet levels (lower than 100,000); 5. gustilo type 3B and higher open fractures; 6. patients that have a contraindication to using Aspirin or Heparin; 7. patients that avoid participating in the study; 8. patients with chronic kidney disease that have lower GFR than 30.

##### Intervention groups

1. Aspirin prescribed 2. Enoxaparin prescribed

##### Main outcome variables

Incidence for deep vein thrombosis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200202046344N1**

Registration date: **2020-09-29, 1399/07/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-29, 1399/07/08**

Update count: **0**

##### Registration date

2020-09-29, 1399/07/08

##### Registrant information

##### Name

Ali Sheikhy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2620 1399

##### Email address

sheikhyali@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effectiveness of Aspirin with Enoxaparin Sodium for prevention of deep vein thrombosis in Tibial fractures

#### Public title

Aspirin in DVT

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Male and Females between 14 and 85 years old Tibial fractures with or without surgery indication

##### Exclusion criteria:

Hip or femur fracture Major fracture except tibia DVT or PTE history Low platelet levels (lower than 100,000) Gustilo type 3B and higher open fractures Patients that have contraindication to use Aspirin or Heparin Patients that avoid to participate in the study Patients with chronic kidney disease that have lower GFR than 30

#### Age

From **14 years** old to **85 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **446**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

All patients were divided into two groups with 1:1 proportion. For the first group, Aspirin will be prescribed, and for the second group, Enoxaparin will be prescribed. Randomization is completely computer-based.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, only the researcher will know about the prescribed medication. Patients and their physicians won't know about anticoagulants that prescribed. hence, patients will get inform that prescribed drugs have anticoagulation effects.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee ,School of Medicine, Tehran University of Medical Sciences

##### Street address

School of Medicine, Tehran University of Medical Sciences, Poor Sina street, Keshavarz blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1967853916

##### Approval date

2020-07-22, 1399/05/01

##### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.255

### Health conditions studied

#### 1

#### Description of health condition studied

Deep Vein Thrombosis

#### ICD-10 code

I82.4

#### ICD-10 code description

Acute embolism and thrombosis of deep veins of lower extremity

### Primary outcomes

#### 1

#### Description

Incidence of deep vein thrombosis in lower extremity

#### Timepoint

At the end of first week, fourth week, 12th week, and 24th week after discharge

#### Method of measurement

Physical examinations an doppler ultra sonography

### Secondary outcomes

#### 1

#### Description

Peptic ulcer disease

#### Timepoint

At the end of first week, fourth week, 12th week, and 24th week after discharge

#### Method of measurement

Short questionnaire with 10 questions

### Intervention groups

#### 1

#### Description

Intervention group: patients with a tibial fracture will

consume 80 mg Aspirin tablets produced by "Pars Daroo" every 12 hours for 35 days to prevent deep vein thrombosis.

**Category**

Treatment - Drugs

**2****Description**

Control group: patients with a tibial fracture will use Enoxaparin 30mg produced by "Osveh" every day for 35 days to prevent deep vein thrombosis.

**Category**

Treatment - Drugs

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

Sina hospital

**Full name of responsible person**

Ali Sheikhy

**Street address**

Imam Khomeini Street

**City**

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**Province**

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**Postal code**

1136746911

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

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraian

**Street address**

6th floor, Tehran University of Medical Sciences, Keshavarz blvd.

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**Email**

msahrai@tums.ac.ir

**Web page address**

<https://vcr.tums.ac.ir/>

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Sheikhy

**Position**

Medical student

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Practitioner

**Street address**

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

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Shafiei

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Sheikhy

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The Trial result will completely present after completion of trial without the participant's personal information.

**When the data will become available and for how long**

after publication

**To whom data/document is available**

for the ones who ask for information

**Under which criteria data/document could be used**

citation to the published article

**From where data/document is obtainable**

Ali Sheikhy email: a-sheikhy@student.tums.ac.ir

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

contact Ali Sheikhy via email. if the condition accepted, data will send.

**Comments**