

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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

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Imam Khomeini Street

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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

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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

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

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Full name of responsible person

Hossein Shafiei

Position

assistant professor

Latest degree

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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