

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison the Injectual Enoxaparin with Oral Rivaroxaban in DVT Prophylaxis of Patients with Pre-Trochanteric Hip Fracture

Protocol summary

Study aim

Comparison the Injectual Enoxaparin with Oral Rivaroxaban in DVT Prophylaxis of Patients with Pre-Trochanteric Hip Fracture.

Design

The clinical trial included a control and parallel group that would not be blind to any subjects after random assignment.

Settings and conduct

No one is blind to this study. Eighty patients in need of hip surgery will receive the intervention and receive either one of the two drugs rivaroxaban or enoxaparin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of peri-trochanteric femoral fractures Exclusion criteria: Heparin sensitivity; endocarditis; liver disease; hematologic diseases

Intervention groups

In this clinical trial study, 80 patients will be enrolled in the study and after randomized assignment, will receive the appropriate intervention (receiving rivaroxaban or enoxaparin). Intervention will be performed at Shohada hospital in Tabriz.

Main outcome variables

Deep vein thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N16**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **prospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 7054

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Injectual Enoxaparin with Oral Rivaroxaban in DVT Prophylaxis of Patients with Pre-Trochanteric Hip Fracture

Public title

Prevention of deep vein thrombosis in pre-trochanteric hip fracture

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of peri-trochanteric femur fracture

Exclusion criteria:

Heparin sensitivity Endocarditis Liver disease Hematologic diseases

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients will be randomly assigned to one of the two groups of enoxaparin or rivaroxaban with the help of an online randomization list (www.randomizer.org).

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Tabriz University of Medical Sciences, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

IR.TBZMED.REC.1398.969

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

Deep vein thrombosis

Timepoint

Once before the intervention and once at the end of the study (30 days later)

Method of measurement

Take a blood test and check the level of D-Dimer in the blood

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the intervention group, after surgery, they will receive 40 mg of enoxaparin subcutaneously for 30 days (one daily). The enoxaparin ampoule will be purchased from Iran Daroo Company ready and given by a nurse every day. Blood will be taken from the patient before the intervention and on the last day of the intervention and serum D-Dimer levels will be measured.

Category

Prevention

2

Description

Control group: patients will be enrolled after random assignment. In the intervention group, after surgery, 10 mg rivaroxaban will be given orally for 30 days (one daily). Rivaroxaban tablets will be purchased from Iran Daroo Company and will be administered daily by a nurse. Blood will be taken from the patient before the intervention and on the last day of the intervention and serum D-Dimer levels will be measured.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Mosayeb Hoseinzadeh

Street address

Azadi Ave, Shohada Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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Associate professor
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Person responsible for updating data

Contact

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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