

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Effect of Rivaroxaban and Enoxaparin in Coagulation Setting for Lower Limb Fracture Surgeries to Prevent Deep Vein Thrombosis and Pulmonary Embolism

Protocol summary

Study aim

The Effect of Rivaroxaban and Enoxaparin in Coagulation Setting for Lower Limb Fracture Surgeries to Prevent Deep Vein Thrombosis and Pulmonary Embolism

Design

Clinical Trial with Control Group, with a parallel group design of 50 patients. Randomized by Cards, Phase:3

Settings and conduct

The Study was Performed in Sabzevar Shahid Beheshti Emdadi Hospital, The Study is done Double Blindly and is done by Cards that the Person who is Allocating it is not aware of its Content. Color Doppler Ultrasound Results are Performed by a Physician who is unaware of the Type of Treatment Assigned. to Blind the Patients, Patients Receiving Enoxaparin are also given Folic Acid Tablet, and Patients Receiving Rivaroxaban are given Distilled Water Injections.

Participants/Inclusion and exclusion criteria

Entry Requirements: All People over the Age of 20 Years who are Candidates for Anticoagulant Therapy Conditions for Denial of Entry: History of Hypersensitivity Reaction to either of the Two Drugs, Severe Bleeding, Pregnancy and Lactation, History of Recent Labor or any Recent Injury, Having Liver Disease or any other Disease that Leads to an Increased Risk of Bleeding.

Intervention groups

Intervention group: People who receive oral Rivaroxaban 10mg Daily for 12 Days and at the same time distilled water were injected into those. Control group: People who receive Enoxaparin Subcutaneous 40mg Daily for 10 Days and at the same folic acid tablet was taken daily into those.

Main outcome variables

Deep Vein Thrombosis; Pulmonary Embolism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041781N1**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **retrospective**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

Registration date

2019-10-14, 1398/07/22

Registrant information

Name

Salar Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4623 4685

Email address

abdis91@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-07, 1397/11/18

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Rivaroxaban and Enoxaparin in Coagulation Setting for Lower Limb Fracture Surgeries to Prevent Deep Vein Thrombosis and Pulmonary Embolism

Public title

Effect of Rivaroxaban on the Prevention of Deep Vein Thrombosis and Pulmonary Embolism

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All People over the Age of 20 Years who are Candidates for Anticoagulant Therapy

Exclusion criteria:

History of Hypersensitivity Reaction to either of the Two Drugs Severe Bleeding Pregnancy and Lactation History of Recent Labor or any Recent Injury Having Liver Disease or any other Disease that Leads to an Increased Risk of Bleeding.

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The Allocation of Treatment is done Randomly by Cards. Individual Randomization Unit.

Blinding (investigator's opinion)

Double blinded

Blinding description

The Allocation of Treatment is done Randomly (The Permutation Block Method that Blinds Donors to Treatment) and by Cards that the Person who is Allocating it is not Aware of its Content. The Results of Color Doppler Ultrasound are not known from the type of Treatment Prescribed, which Includes Enoxaparin 40 mg Subcutaneous Daily and Rivaroxaba 10 mg Daily Oral. The Person Who Cares for the Clinic is also not Aware of the Contents of the Cards. The Examination of the Extended outcome Include Deep Vein Thrombosis or Pulmonary Embolism after Surgery, Which is Evaluated one Month after Starting Treatment and Observation of the Symptoms of Deep Venous Thrombosis (Warmth, Pain, Swelling, Especially the Back of the Leg) and Pulmonary Embolism (Dyspnea, Pleuretic Pain, Orthopnea), The Ultrasound Results are not known by the Medical Specialist who is Assigned the Type of Treatment. In Order to Blind the Evaluator of Treatment, an Attempt was made to use a Separate

Individual from the Therapist (who is Medical Student in this Study). to Blind the Patients, Patients Receiving Enoxaparin are also given Folic Acid Tablet, and Patients Receiving Rivaroxaban are given Distilled Water Injections.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Sabzevar University of Medical Sciences

Street address

Campus of the University of Medical Sciences, Above the Shohadaye Gomnam, Shohadaye Hastei Blvd.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114- 96179131

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.MEDSAB.REC.1397.076

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 deep vessels of lower extremities Deep vein thrombosis

2**Description of health condition studied**

Pulmonary Embolism

ICD-10 code

i26

ICD-10 code description

Pulmonary embolism

Primary outcomes

1

Description

Deep Vein Thrombosis

Timepoint

One Month after Receiving Treatment

Method of measurement

Examinations and Color Doppler Ultrasound

2

Description

Pulmonary Embolism

Timepoint

One Month after Receiving Treatment.

Method of measurement

Examinations and Color Doppler Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People who receive oral Rivaroxaban 10mg Daily for 12 Days then at the same time, distilled water were injected to those

Category

Prevention

2

Description

Control group: People who receive Enoxaparin Subcutaneous 40mg for 10 Days then at the same time, a folic acid tablet daily was taken to those

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Emdad Hospital

Full name of responsible person

salar abdi

Street address

Razi street, Shahid Beheshti Emdad Hospital

City

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Razavi Khorasan

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9617748189

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Email

salar.abdi.1371@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshte Ghorat

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Campus of the University of Medical Sciences, Above the Shohadaye Gomnam, Shohadaye Hastei Blvd

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Drghorat@gmail.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

salar abdi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available