Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

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

Public title
Effect of Rivrvoxaban 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 Entended 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 Bblind 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
Sabzevar
Province
Razavi Khorasan
Postal code
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
Street address
Campus of the University of Medical Sciences, Above the Shohadaye Gomnam, Shohadaye Hastei Blvd
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Fax
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Email
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 updating data

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General Practitioner
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Web page address

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