Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of Rivaroxaban and Enoxaparin to Prevent Deep Vein Thrombosis in Patients with Pelvic Fracture

Protocol summary

Study aim

The purpose of this study is to prevent deep vein thrombosis in patients with pelvic fracture, that will be compared efficacy of rivaroxaban with enoxaparin. First of all, all participants will be advised to refer to the emergency department and inform to physician If there are any signs of pain in the leg or abnormal bleeding. For patients with leg pain radiology and abnormal bleeding will be tested for coagulation abnormalities.

Design

The sample size is 112 patients with pelvic fracture which will be assigned into study groups using blocked randomization method. The study design is parallel. Participants and physicians that evaluated the outcomes of the study will be blinded of the interventions that take by the participants.

Settings and conduct

Patients will be included in the study, with symptoms of pelvic fracture whose fracture has been confirm whit radiology and does not need to surgery. Participants will be divided into study groups. Patients will be blinded to receiving intervention from other participants in the study and physicians will also be blinded of the intervention received by each patient.

Participants/Inclusion and exclusion criteria

The main include criteria into the study is patients with pelvic fractures that do not need to surgery. Taking anticoagulant drugs for at least one week, having kidney or liver disease are excluded criteria.

Intervention groups

Patients will be take 10 milligrams rivaroxaban at once daily for two weeks. Patients in the control group will be take 40 milligrams enoxaparin at once a day for seven days.

Main outcome variables

The main outcomes are in this study deep venous thrombosis, abnormal bleeding during in use of interventions and the time of follow-up. In addition to reporting patients when viewing each symptom, we will take information from participants at least once every two weeks by phone call.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042419N1**
Registration date: **2019-02-09, 1397/11/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**
Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

Peyman Hafezimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 5327

Email address

hafezimoghadam.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-24, 1397/11/04

Expected recruitment end date

2019-03-10, 1397/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Rivaroxaban and Enoxaparin to Prevent Deep Vein Thrombosis in Patients with Pelvic Fracture

Public title
Comparison of Rivaroxaban and Enoxaparin to Prevent Deep Vein Thrombosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Pelvic Fracture No need for surgery

Exclusion criteria:
Having kidney disease Use of anticoagulation drugs in less than a week Being pregnant Being in duration of breastfeeding Liver disease Having a head trauma

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were assigned after selected for study by block randomization method to Rivaroxaban and Enoxaparin groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will be blinding of the type of intervention received by other patients in this study. In addition, physician that examining the outcomes of the study will be blinded of the type of drugs.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-12-16, 1397/09/25

Ethics committee reference number
IR.IUMS.REC.1397.676

Health conditions studied

1

Description of health condition studied
Pelvic Fracture

ICD-10 code
S32.7

ICD-10 code description
Multiple fractures of lumbar spine and pelvis

Primary outcomes

1

Description
Deep Vein Thrombosis

Timepoint
Two times from the beginning of the study to distance two weeks

Method of measurement
Having any signs of pain in the leg

Secondary outcomes

1

Description
Bleeding

Timepoint
Two times from the beginning of the study to distance two weeks

Method of measurement
Any type of abnormal bleeding will be recorded in the during the study

2

Description
Cost of intervention consumption

Timepoint
Deal of Drug consumption in during treatment

Method of measurement
Mean of consumption cost

Intervention groups

1

Description
Intervention group: A dose of 10 milligrams Rivaroxaban will be giving orally once a day for two weeks.
Category
Treatment - Drugs

2

Description
Control group: Enoxaparin will be giving at a dose of 40 milligrams once a day subcutaneously for seven days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Shaghayegh Sharifian
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9260
Email
sharifian65@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Malakouti
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Peyman Hafezimoghadam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St.
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6652 5327
Email
hafezimoghadam@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Peyman Hafezimoghadam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran

Postal code
1449614535
Phone
+98 21 6652 5327
Email
hafezimoghadam@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Peyman Hafezimoghadam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St.
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6652 5327
Email
hafezimoghadam@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not 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
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.
When the data will become available and for how long
Availability 6 months after the end of study
To whom data/document is available
Emergency medicine and orthopedic specialists
Under which criteria data/document could be used
In the case of comparison with other similar trials or treatment
From where data/document is obtainable
Iran University of Medical Sciences
What processes are involved for a request to access data/document
By referring to the central library of Iran University of Medical Sciences can access to the text of the final report or article.
Comments