Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative efficacy and safety of rivaroxaban and subcutaneous enoxaparin in perevention of venous thrombo embolic events after spinal instrumentation

Protocol summary

Study aim
In this study, hemorrhagic events caused by taking rivaroxaban and enoxaparin will be investigated.
Design
A controlled clinical trial, with parallel groups, double blind, randomized, For randomization the rand function of Excel software was used.
Settings and conduct
This study will be performed in educational and medical centers of Al-Zahra, Isfahan, Iran.
Participants/Inclusion and exclusion criteria
Inclusion criteria: all patients who undergo spinal device placement; patient consent to participate in the study; the patient's high risk of venous thromboembolism. Exclusion criteria: use of anticoagulant in the last 3 months; urine test with purpura-positive blood or cutaneous hematoma of active bleeding or high risk of bleeding; presence of active cancer as an underlying disease or cancer treated in the last 6 months; hospitalization in home and inactivity for more than 3 days; body mass index more than 35; history of PTE and DVT and smoking more than 20 cigarettes a day.
Intervention groups
The intervention group received 15 mg rivaroxaban tablets and the control group received 1 mg / kg / day subcutaneous enoxaparin ampoule.
Main outcome variables
Occurrence of venous thromboembolism

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211109053014N1**
Registration date: **2021-12-19, 1400/09/28**
Registration timing: **registered_while_recruiting**
Last update: **2021-12-19, 1400/09/28**
Update count: **0**
Registration date
2021-12-19, 1400/09/28

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-12-06, 1400/09/15
Expected recruitment end date
2022-02-20, 1400/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative efficacy and safety of rivaroxaban and subcutaneous enoxaparin in perevention of venous thrombo embolic events after spinal instrumentation

Public title
Efficacy and safety of rivaroxaban and subcutaneous enoxaparin after spinal surgery
Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing spinal cord surgery Patient consent to participate in the study High risk of the patient for venous thromboembolism

Exclusion criteria:

Consumption of anticoagulants in the last 3 months Urine test with purpura-positive blood or cutaneous hematoma with active bleeding or high risk of bleeding Existence of active cancer as an underlying disease or cancer treated in the last 6 months Hospitalization and inactivity for more than 3 days Smoking more than 20 cigarettes a day Having a body mass index higher than 35 Pulmonary embolism and lower venous thrombosis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Random function of Excel software based on patient file number will be used for randomization. Patients undergoing spinal surgery were included in the Excel program based on the file number and were divided into case and control groups based on the random button. There were two groups of 35 people in total. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want 200 people in each group. As a result, sequences 1 to 2 should be repeated 100 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 100 for repeating the sequence. In this way, 200 pieces will be produced.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

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Province

Isfehan

Postal code

8174673461

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.MUI.MED.REC.1399.578

Health conditions studied

1

Description of health condition studied

Intravenous thromboembolism

ICD-10 code

O88.23

ICD-10 code description

Thromboembolism in the puerperium

Primary outcomes

1

Description

Intravenous Thromboembolism

Timepoint

In this study, hemorrhagic events caused by rivaroxaban and enoxaparin before surgery and 4 weeks after.

Method of measurement

According to the patient's clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of Rivarxaban 15 mg tablets once a day for 4 weeks after surgery from Dr. Obidi's factory

Category

Prevention

2

Description

Control group: Enoxaparin subcutaneous ampoule 1 mg / kg / day For 4 weeks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital
Full name of responsible person
Mehdi Shafiei
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Sponsors / Funding sources

1

Sponsor

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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
Esfahan 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
Esfahan University of Medical Sciences
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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
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