

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

Babak Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 7260 6626

Email address

resident_neurosurgeon@yahoo.com

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

City
Isfahan

Province
Isfahan

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

Street address

Al-Zahra hospital, Sofeh St., Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Mehdishafiei82@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjuye Javanmardi

Street address

Isfahan University of Medical Sciences, hezar jarib S.T

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

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

Full name of responsible person

Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Babak Karami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

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

Sharing plan**Deidentified Individual Participant Data Set (IPD)**