

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of efficiency and safety of rivaroxaban and subcutaneous enoxaparin in the prevention of venous thromboembolic events after spinal instrumentation surgery

Protocol summary

Study aim

Comparison of efficiency and safety of rivaroxaban and subcutaneous enoxaparin in the prevention of venous thromboembolic events after spinal instrumentation surgery

Design

A randomized, double-blind, controlled clinical trial

Settings and conduct

Patients undergoing spinal surgery referring to the Imam Reza Hospital in Tabriz City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization. This trial will be double-blinded so that neither the treatment assessor nor the data analyzer will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have undergone spine surgery and have no previous history of venous thromboembolism. Exclusion criteria: Patient dissatisfaction, patients with coagulation disorders, People with underlying diseases such as high blood pressure, diabetes and severe osteoporosis, Patients with kidney failure

Intervention groups

Intervention group 1: People who receive oral Rivaroxaban (Aboreihan Company) 10 mg twice a day after surgery for one week; Intervention group 2: people who receive subcutaneous Enoxaparin (Tehran Chemical Company) 40 mg daily for one week after surgery.

Main outcome variables

Inflammation, pain, differences in organ size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N16**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficiency and safety of rivaroxaban and subcutaneous enoxaparin in the prevention of venous thromboembolic events after spinal instrumentation

surgery

Public title

Efficiency of rivaroxaban and enoxaparin in the prevention of venous thromboembolic events

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have undergone spine surgery and have no previous history of venous thromboembolism .

Exclusion criteria:

Patient dissatisfactionsm patients with coagulation disorders People with underlying diseases such as high blood pressure, diabetes and severe osteoporosis
Patients with kidney failure

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individuals were assigned to two groups using the permutation block method(without replacement). In this method, A represents the individual receiving the rivaroxaban and B represents the individual in the subcutaneous enoxaparin group. Considering the quadruple block; they were classified into AABB, ABAB, ABBA, BAAB BBAA, and BABA permutations, and by random selection from permutation, patients were classified.

Blinding (investigator's opinion)

Double blinded

Blinding description

The randomization will be concealed using a sealed envelope prior to the start of the study, and the evaluator and the statistical analyst will be completely blind to the process. Upon arrival, individuals will be assigned to either the rivaroxaban or the subcutaneous enoxaparin group based on the letters A and B in their packet. the therapist, in the absence of evaluators, will provide the desired treatment based on the letter in the packet. In order to allocate concealment, the type of intervention will be written on paper and placed in matte, and packed envelopes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Medical School

Street address

Floor 3, Center building N 2, Tabriz university of medical sciences, Golgasht street.

City

Tabriz

Province

East Azarbaijan

Postal code

5159115705

Approval date

2023-01-09, 1401/10/19

Ethics committee reference number

IR.TBZMED.REC.1401.917

Health conditions studied

1

Description of health condition studied

Spinal fusion

ICD-10 code

M99.3

ICD-10 code description

Osseous stenosis of neural canal

Primary outcomes

1

Description

Inflammation

Timepoint

after surgery daily for 10 days

Method of measurement

Clinical evaluation

2

Description

pain

Timepoint

after surgery daily for 10 days

Method of measurement

Clinical evaluation

3

Description

Differences in organ size

Timepoint

after surgery daily for 10 days

Method of measurement

Clinical evaluation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: People who receive oral Rivaroxaban (Aboreihan Company) 10 mg twice a day after surgery for one week.

Category

Treatment - Drugs

2**Description**

Control group: people who receive subcutaneous Enoxaparin (Tehran Chemical Company) 40 mg daily for one week after surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurosurgery Ward of Emem Reza hospital

Full name of responsible person

Dr. Ali Meshkini

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Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

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Web page address<https://imamreza.tbzmed.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Joyban

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Vice chancellor for research, Daneshgah street, Tabriz

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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

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Farhad Mirzaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

A portion of the data that represents the final outcome

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

For modeling and guidance

From where data/document is obtainable

The person responsible for updating study information

What processes are involved for a request to access data/document

The applicant provides information about their application via email. Up to two weeks after the request, if accepted, documents or data files will be sent.

Comments