

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 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 (Abo-reihan 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

**Street address**

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

**City**

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**Province**

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**Email**

meshkinia@yahoo.com

**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

**Street address**

Vice chancellor for research, Daneshgah street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

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**Email**

research-vice@tbzmed.ac.ir

**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**

Neurosurgery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr Ali Meshkini  
**Position**  
Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Ali Salami  
**Position**  
Resident  
**Latest degree**  
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**Other areas of specialty/work**  
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**Province**  
East Azarbaijan  
**Postal code**

5166614756

### Phone

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### Email

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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