Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of enoxaparin and aspirin on the prevention of deep vein thrombosis after spinal surgery

Protocol summary

Study aim
Comparison of the effects of enoxaparin and aspirin in preventing deep vein thrombosis after spine surgery

Design
Clinical trial with control group with parallel groups, double blind, randomized on 100 patients. For randomization, restricted randomization was used .

Settings and conduct
A clinical trial with a control group with parallel groups, double-blind, randomized, is conducted on 100 patients who have undergone spinal surgery in Shahid Ghayab Hospital of Mashhad, and Caprini criteria of 5 and above have been obtained for them.In the intervention group, ASA is administered 24 hours after surgery, and in the control group, Enoxaparin is prescribed, and the occurrence of DVT is checked after 7 days. In this study, the evaluator, the analysts and the allocation of the sample data to the groups are blinded. Each patient is transferred to a group by a collaborator who has no knowledge of the patient and the treatment method, and the information is recorded in sealed envelopes. At the beginning of the prophylaxis treatment, the envelope is opened by the researcher and the medicine is prescribed.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 70 years who underwent spine surgery at Shahid Ghayab Hospital and have a Caprini score of 5 or more and did not have DVT or pulmonary embolism before the surgery

Intervention groups
In the intervention group, aspirin tablets with a dose of 81 mg daily are used orally. The administration of drugs starts 24 hours after the end of the surgery to prevent bleeding at the operation site and continues for 7 days after the operation. In the control group, for the prevention of DVT, enoxaparin with a dose of 40 mg is prescribed as a subcutaneous injection for 7 days. Subsequently, on the seventh day after surgery to diagnose DVT, the venous venous Doppler ultrasound is performed.

Main outcome variables
Occurrence or absence of DVT

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221014056171N1**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**
Update count: **0**

Registration date
2023-01-25, 1401/11/05

Registrant information

Name
Amir Kavian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3802 6232

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kavianam971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-21, 1401/08/30

Expected recruitment end date
2023-03-19, 1401/12/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of enoxaparin and aspirin on the prevention of deep vein thrombosis after spinal surgery

Public title

Comparison of the effect of enoxaparin and aspirin on the prevention of deep vein thrombosis after spinal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 70 years who underwent spine surgery at Shahid Kamyab Hospital and the Caprini score is 5 or more and did not have DVT or pulmonary embolism before the surgery

Exclusion criteria:

Lack of patient consent to enter the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, restricted randomization using the random allocation rule is used.For this purpose, the total sample size is 100 people and each group is 50 people.For each person, one envelope is removed from the total number of envelopes, which is the group assigned to the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each patient is transferred to a group (intervention or control) by a collaborator who has no knowledge of the patient and the treatment method, and the information is recorded in sealed envelopes. At the beginning of the prophylaxis treatment, the envelope is opened by the researcher and the medicine is prescribed

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Shahid Kamyab hospital , Fadayaneslam37474 Ave. , Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

3747491666

Approval date

2022-07-11, 1401/04/20

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.515

Health conditions studied

1

Description of health condition studied

Deep venous thrombosis

ICD-10 code

I80.3

ICD-10 code description

Phlebitis and thrombophlebitis of lower extremities, unspecified

Primary outcomes

1

Description

Occurrence or absence of deep venous thrombosis

Timepoint

Color doppler venous ultrasound of the lower limbs 7 days after surgery

Method of measurement

Color doppler venous ultrasound of the lower limbs

Secondary outcomes

1

Description

Bleeding or hematoma at the surgical site

Timepoint

Seven days after surgery

Method of measurement

Observation and palpation by the researcher

Intervention groups

1

Description

Intervention group: In the intervention group, aspirin tablets with a daily dose of 81 mg are used orally.The administration of drugs starts 24 hours after the end of the surgery to prevent bleeding at the operation site and continues for 7 days after the operation.If the patient is hospitalized while taking the drug, the monitoring of drug use and side effects will be done by the researcher, and if the patient is not hospitalized, by one of the first-degree relatives trained by the researcher.In the use of drugs prescribed for patients, drugs of the same brand will be prescribed.After that, on the seventh day after surgery, a venous Doppler ultrasound of the lower limbs is performed to diagnose DVT.To minimize the error caused by the radiologist in performing ultrasound, all ultrasounds will be performed by an experienced radiologist.

Category

Treatment - Drugs

2

Description

Control group: In the control group, for the prevention of DVT, enoxaparin with a dose of 40 mg is prescribed as a subcutaneous injection for 7 days.Other measures are similar to the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Khamyab Hospital, Mashhad

Full name of responsible person

Amir Kavian

Street address

Fadayaneslam Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

مجید غیور مبرهن

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amir Kavian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Totals of participants and outcome information are shared after de-identification of individuals
When the data will become available and for how long
Access starts one year after results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data will be available for use in scientific studies
From where data/document is obtainable
Amir Kavian, Neurosurgery resident,Shahid Kamyab hospital,Mashhad,Iran
What processes are involved for a request to access data/document
Checking the identity of the data requester through the ID card and also checking the study that is going to be done.
Comments