Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effectiveness of aspirin in preventing DVT after lumbar spinal stenosisSurgeries

Protocol summary

Study aim
Evaluation of the effectiveness of aspirin in preventing (DVT) Deep Vein Thrombosis after lumbar spinal stenosisSurgeries

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 102 patients will be candidates for spinal stenosis decompression surgery. Excel software rand function will be used for randomization.

Settings and conduct
Patients over 40 years of age who are candidates for spinal stenosis decompression surgery who will refer to the orthopedic clinic of Shafa Yahyaian Hospital affiliated to Iran University of Medical Sciences will be included in the study. Sampling of patients is done by available and easy sampling. Patients are then randomly assigned to intervention and control groups. Patients will be blind to researchers and analyzers of the results of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: patients over 40 years of age, candidates for decompression of spinal canal stenosis and Informed consent to participate in the study. Exclusion criteria include: Prohibition of the use of aspirin and associated musculoskeletal disorders including severe osteoarthritis, rheumatoid arthritis, fibromyalgia.

Intervention groups
Intervention group: Patients who have undergone spinal stenosis decompression and will receive 325 mg oral aspirin twice a day for 2 to 4 weeks, and the control group includes patients who have undergone spinal stenosis decompression and received oral placebo. will do.

Main outcome variables
Incidence of DVT after lumbar spinal stenosis surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210825052290N1**
Registration date: **2021-12-06, 1400/09/15**
Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**
Update count: **0**

Registration date
2021-12-06, 1400/09/15

Registrant information

Name
Ali Habibollahzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 3354 2041

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alihabibollahzadeh.ortho@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of aspirin in preventing DVT after lumbar spinal stenosisSurgeries

Public title
The effectiveness of aspirin in preventing DVT after lumbar canal stenosis Surgeries
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 40 years of age who have undergone decompression of spinal canal stenosis Patients' informed consent
Exclusion criteria:
Prohibition of aspirin use Concomitant musculoskeletal diseases including severe osteoarthritis, rheumatoid arthritis, fibromyalgia
Age
From **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
Random chain construction of two groups of 51 A (intervention group) and B (control group) using Excel software will be used. In a column of 51 letters A and 51 letters B and in the adjacent column with the Rand command, make 102 random numbers. Arrange both columns in random order from large to small. The sequence of letters A and B will be the random sequence used.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are randomly assigned to intervention and control groups. In such a way that patients, the prescribing physician, and the analyzer will be blind to the groups that have received the drug or placebo.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-11-21, 1400/08/30
Ethics committee reference number
IR.IUMS.REC.1400.766

Health conditions studied

1

Description of health condition studied
Deep Vein Thrombosis
ICD-10 code
I82.4
ICD-10 code description
Acute embolism and thrombosis of deep veins of lower extremity

Primary outcomes

1

Description
Frequency of DVT after lumbar spinal stenosis
Timepoint
After the intervention and 3 months after taking aspirin
Method of measurement
Intravenous color Doppler ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Candidates for decompression stenosis surgery who will receive 325 mg oral aspirin twice daily for 3 weeks after surgery.
Category
Prevention

2

Description
Control group: Yamaran is a candidate for canal stenosis decompression surgery who will receive oral placebo twice a day for 3 weeks after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Yahyaian Hospital

Full name of responsible person
Ali Habibollahzadeh

Street address
Tehran, Baharestan Square, Mojahedin-e-Islam St., Shafayehiaian Educational and Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hossein Kiwani

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research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Ali Habibollahzadeh

Position
asistant professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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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
Unidentifiable personal data of participants will be shared upon request upon completion of the study. The protocol of surgery and study will be provided to the researchers in the form of a report after the end of the study. Statistical analysis of the data of this study will be shared in the form of a report after the end of the study. Informed design consent form, study clinical reports and codes used in the analysis will be shared in the form of a report at the end of the study. Part of the data, such as information about the main outcome or the like, will be published collectively without identifying individuals in the form of an article
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
University researchers
Under which criteria data/document could be used
Use to promote knowledge and researchers without permission to manipulate documents
From where data/document is obtainable
corresponding
What processes are involved for a request to access data/document
Send a written request and then review and if the request is approved, the documents will be delivered. (Maximum one month)
Comments