

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of low and high dose aspirin in prevention of venous thromboembolism after hip and knee arthroplasty

Protocol summary

Study aim

Comparison of low and high dose aspirin in prevention of venous thromboembolism after arthroplasty of hip and knee joints

Design

This is a double-blind, randomized clinical trial study, with parallel groups and without control group. 540 patients who underwent hip and knee arthroplasty in Sina, Shariati and Imam Khomeini hospitals are divided into two groups. In this study, venous thrombosis is monitored within 6 weeks. Suspected cases of venous thrombosis are diagnosed by color Doppler ultrasound and cases suspected of pulmonary embolism are scanned by perfusion or CT pulmonary angiography.

Settings and conduct

In this study, in hospitals including Sina Hospital, Shariati Hospital and Imam Khomeini Hospital, patients who underwent hip and knee arthroplasty are divided into two groups. In this study, they receive the mentioned drugs within 6 weeks after the operation and during this clinical signs of Venous thrombosis is observed for 6 weeks. Sampling is done by available method. The study is double-blind and in terms of medication received, the surgeon and the patient do not know what dose of medication to receive for the patient's prophylaxis.

Participants/Inclusion and exclusion criteria

patients candidate for hip and knee arthroplasty liver dysfunction any contraindication for anticoagulant therapy indication for enoxaparin therapy active cancer

Intervention groups

Patients who underwent hip and knee arthroplasty, receive 80 mg aspirin twice daily in one group and 325 mg aspirin twice daily in another group after surgery. thrombosis will be monitored in 6 weeks.

Main outcome variables

deep vein thrombosis, pulmonary embolism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046174N2**

Registration date: **2021-01-09, 1399/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-09, 1399/10/20**

Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Hossein Shafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1297

Email address

dr_hshafiei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of low and high dose aspirin in prevention of venous thromboembolism after hip and knee arthroplasty		assistant) and patient don't know the dose of prophylactic medicine .After surgery doctor will be informed .Hospitalization time, surgeon, pain control protocol ,anesthesia technique and volume of intraoperative lavage are similar in both groups and postoperative rehabilitation is the same ..	
Public title	Comparison of aspirin for the prevention of venous thrombosis after knee and pelvic orthoplasty	Placebo	Not used
Purpose	Other	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: patients candidate for hip and knee arthroplasty Exclusion criteria: liver dysfunction any contraindication for anticoagulant therapy indication for enoxaparin therapy as anticoagulant history of deep vein thrombosis active cancer	Other design features	comparison
Age	No age limit	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Care provider	Ethics committee	
Sample size	Target sample size: 540	Name of ethics committee	Ethics Committee Ethics Committee of Tehran University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Tehran Sina Hospital, Men's Orthopedic Department
Randomization description	In this study, the law of random allocation based on computer program randomization is used to randomize the treatment groups, so that 540 samples are randomly assigned to group A (aspirin 80) and B (aspirin 320) (Random allocation table). In this way, patients attended to the hospital for surgery receive a single code and based on that code, one of the two treatment groups is considered for them. Also, in order to blind the study, envelopes containing cards with numbers 1 to 540 (number of study sample volumes) are prepared and the lids of the letter envelopes are glued and placed in a box. At the beginning of the registration, according to the order of entry of eligible participants to the study , one of the envelopes opened and its assigned group revealed based on the number registered on the participant card. It should be noted that these envelopes are only for one person and that number cant any longer be taken. Example: For the first patient, one of the envelopes in the box is selected. It is seen after opening box number 25. After referring to the random allocation table, it is observed that patient 25 should receive drug B, which is defined as aspirin 320. In order to ensure the status of the allocations and non-repetition, after selecting the groups and knowing the status of the treatment, the information will be inserted in a table (like the table below) .	City	Tehran
Blinding (investigator's opinion)	Double blinded	Province	Tehran
Blinding description	The study is double-blind ,means both surgeon (specialist	Postal code	۱۱۳۶۷۴۶۹۱۱
		Approval date	2020-11-28, 1399/09/08
		Ethics committee reference number	IR.TUMS.SINAHOSPITAL.REC.1399.073
		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	pulmonary thromboembolism
		Timepoint	operative day, 6 weeks after surgery
		Method of measurement	physical examination and history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients who underwent total knee or hip arthroplasty receive 80 mg aspirin twice a day for 4-6 weeks.

Category

Treatment - Drugs

2

Description

Intervention group2 : patients who underwent total knee or hip arthroplasty receive 325mg aspirin twice a day for 4-6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr. Mohammad Rastegar

Street address

Imam Khomeini St., Sina Hospital, Building No. 4, first floor

City

Tehran

Province

Tehran

Postal code

113746911

Phone

+98 21 6312 1417

Email

Drmrastegar2342@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Hasan abad sq. sina hospital

City

Tehran

Province

Tehran

Postal code

113746911

Phone

+98 21 6312 1417

Email

drmrastegar23432@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rastegar

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Tehran, Imam Khomeini St., Sina Hospital, Men's Orthopedic Department

City

Tehran

Province

Tehran

Postal code

113746911

Phone

+98 21 6312 1417

Email

Drmrastegar2342@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Hossein Shafeie

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Imam Khomeini St., not far from Hassanabad Square,
Sina Hospital, Building No. 4, first floor, men's
orthopedic ward

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Province

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orthopedic ward

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Phone

63121297

Email

Drmrastegar2342@gmail.com

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

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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rastegar

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Imam Khomeini St., not far from Hassanabad Square,