

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

A clinical trial to compare the effect of rivaroxaban with enoxaparin on the prophylaxis of venous thromboembolism in patients undergoing knee or hip arthroplasty surgery.

Protocol summary

Study aim

The comparison of the effect of rivaroxaban with enoxaparin on prophylaxis of venous thromboembolism in patients undergoing knee or hip arthroplasty surgery.

Design

In this double-blind clinical trial, 150 patients who were candidate for hip or knee arthroplasty surgery were assigned into parallel groups using the table of random numbers.

Settings and conduct

The patients are candidates for hip or knee arthroplasty surgery at Shafa Yahyaian Hospital, Tehran, Iran. In this double-blind study, the clinical care provider and data collector were blind regarding the group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients who are more than 18 years of age, and those who are candidate for hip or knee arthroplasty surgery. Exclusion criteria: The patients with severe side effects of a drug, moderate to severe hepatic disorder, and cardiovascular diseases were excluded from the study.

Intervention groups

The intervention group I will receive 40 mg enoxaparin (Rolexan, Ronakdaru, Iran) subcutaneously on a daily basis for 14 days, followed by the administration of 325 mg aspirin daily for 14 days. The intervention group II will receive 10 mg rivaroxaban (Axabin, Iran Hormone, Iran) orally on a daily basis for 12 days, followed by the administration of 325 mg aspirin daily for 14 days.

Main outcome variables

Deep vein thrombosis; the side effects of wounds; wound infection; gastrointestinal complications; skin complications; severe bleeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161121031003N4**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **prospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Kaveh Gharanizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2000

Email address

gharanizadeh.k@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-18, 1398/12/28

Expected recruitment end date

2020-05-17, 1399/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effect of rivaroxaban with enoxaparin on the prophylaxis of venous thromboembolism in patients undergoing knee or hip arthroplasty surgery.

Public title

The effect of rivaroxaban and enoxaparin on the prophylaxis of venous thromboembolism

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

More than 18 years of age Who are candidate for hip or knee arthroplasty surgery

Exclusion criteria:

Severe side effects of a drug Moderate to severe hepatic disorder Cardiovascular diseases

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly assigned into two groups of 75 patients with blocks of 2 and 4 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sample selection based on a statistical analysis system (SAS), computer software. Sequentially numbered sealed opaque envelopes will be used to conceal the sequencing. Accordingly, the participants were given codes and assigned into the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients are candidates for hip or knee arthroplasty surgery at Shafa Yahyaian Hospital, in Tehran, Iran. In this single-blind study, the responsible individuals for data collection are unaware of the type of drug in the selection of participants.

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

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-07-31, 1395/05/10

Ethics committee reference number

IR.IUMS.FMD.REC.1395.347

Health conditions studied

1

Description of health condition studied

Knee or hip arthroplasty surgery

ICD-10 code

T84

ICD-10 code description

Complications of internal orthopaedic prosthetic devices, implants and grafts

Primary outcomes

1

Description

Deep vein thrombosis

Timepoint

6, 12, and 24 weeks after the intervention

Method of measurement

Doppler ultrasound

Secondary outcomes

1

Description

The side effects of wounds

Timepoint

6, 12, and 24 weeks after the intervention

Method of measurement

Questionnaire

2

Description

Wound infection

Timepoint

6, 12, and 24 weeks after the intervention

Method of measurement

Questionnaire

3

Description

Gastrointestinal complications

Timepoint

6, 12, and 24 weeks after the intervention

Method of measurement

Questionnaire

4

Description

Skin complications

Timepoint

6, 12, and 24 weeks after the intervention

Method of measurement

Questionnaire

5

Description

Severe bleeding

Timepoint

6, 12, and 24 weeks after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

The intervention group I will receive 40 mg enoxaparin (Rolexan, Ronakdaru, Iran) subcutaneously on a daily basis for 14 days, followed by the administration of 325 mg aspirin daily for 14 days.

Category

Prevention

2

Description

The intervention group II will receive 10 mg rivaroxaban (Axabin, Iran Hormone, Iran) orally on a daily basis for 12 days, followed by the administration of 325 mg aspirin daily for 14 days.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shafa Yahyaian Hospital

Full name of responsible person

Kaveh Gharanizadeh

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seeyed Abbas Motevalian

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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

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

Mostafa Salehpour

Position

Orthopedics

Latest degree

Specialist

Other areas of specialty/work

Orthopedics
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

All data, including the primary and secondary outcomes, can be shared.

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Our data will be available only to the researchers working in academic and scientific centers.

Under which criteria data/document could be used

Our data will be available to the researchers working in academic and scientific centers.

From where data/document is obtainable

Mostafa Salehpour provides the data analysis to the applicants via email: gharanizadeh.k@iums.ac.ir

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

Applicants can be informed about the final results by sending an email to the given researcher and receiving a response within a week.

Comments