

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison study on Effectiveness of Aspirin 80, Aspirin 325, Enoxaparin and Rivoroxaban in Prevention of Coagulopathy after Total Knee Arthroplasty

Protocol summary

Study aim

The results of this study can be used to select the drug with the highest efficacy and the least complications to prevent postoperative coagulation disorders and to apply in national guidelines.

Design

Clinical trial with pragmatic control group, without blindness and randomization

Settings and conduct

Patients who are candidates for knee replacement surgery at Besat hospital of Hamadan

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with definite diagnosis of osteoarthritis, rheumatoid arthritis, or knee joint destruction by knee specialist who are candidates for knee replacement surgery due to pain and severe motor limitation. Non-inclusion criteria for patients who have a history of allergic skin, respiratory or allergic to aspirin; have history of the anticoagulant drugs and hemorrhagic diseases, and have a history of malignancy and liver and kidney disease.

Intervention groups

Patients with definite diagnosis of osteoarthritis, rheumatoid arthritis or destruction of the articular surface

Main outcome variables

Deep Vein Thrombosis; Pulmonary Thromboembolism; Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041784N1**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Esmail Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3423 3331

Email address

esmailsadeghi93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-23, 1397/10/02

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison study on Effectiveness of Aspirin 80, Aspirin 325, Enoxaparin and Rivoroxaban in Prevention of Coagulopathy after Total Knee Arthroplasty

Public title

Effectiveness of Aspirin 80, Aspirin 325, Enoxaparin and Rivoroxaban in Prevention of Coagulopathy after Total Knee Arthroplasty

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with definite diagnosis of osteoarthritis, rheumatoid arthritis or joint destruction Patients are candidates for knee replacement because of pain and severe motor limitation

Exclusion criteria:

History of skin allergy, respiratory or allergic to aspirin
History of the use of anticoagulant and hemorrhagic diseases
History of malignancy
History of liver and kidney disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into four groups. Blind randomization method is used to assign patients to 4 groups. The block size is 8 according to the number of groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

Street address

Ayatalah Motahari Blvd., Resalat Square, Besat Hospital, Hamedan

City

Hamadan

Province

Hamadan

Postal code

6514745411

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.UMSHA.REC.1397.704

Health conditions studied**1****Description of health condition studied**

osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes**1****Description**

Deep vein Thrombosis

Timepoint

1, 2 and 6 week

Method of measurement

Venous Doppler Ultrasonography

Secondary outcomes**1****Description**

pulmonary thromboembolic

Timepoint

1, 2 and 6 week

Method of measurement

CT Angiography

Intervention groups**1****Description**

Intervention group: First group: 80 mg of aspirin, acetylsalicylic acid, twice daily, oral, up to three weeks.

Category

Treatment - Surgery

2**Description**

Intervention group: . Second group: 325 mg of Aspirin, acetylsalicylic acid, daily, one, oral, up to three weeks

Category

Treatment - Surgery

3**Description**

Intervention group: Third group of Enoxaparin, 40 mg, low molecular weight heparin, once daily, subcutaneous injection, up to three weeks

Category

Treatment - Surgery

4**Description**

Intervention group: .Fourth group:10 mg of Ravaroxaban, Oxazolidone, daily, one, oral, up to three weeks

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat hospital

Full name of responsible person

Gholamreza Ghorbaniamjad

Street address

Ayatolah Motahari Blvd, Resalat Square, Besat hospital

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esmailsadeghi93@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Vice chancellor for research and technology, Hamadan University of Medical Sciences, across the Mardom Park, Shahid Fahmideh Blvd

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info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Gholamreza Ghorbaniamjad

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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

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Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

A portion of the data can be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academics centers

Under which criteria data/document could be used

People who have the same study with us

From where data/document is obtainable

contact with correspond

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

First, send an application by email or other communication channels to the author, then submit the application to the University of Science and Technology Vice-Chancellor for Research and Technology.

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

Hamedan University of Medical Sciences

Full name of responsible person

Esmail Sadeghi

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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