# 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**
Esmaeil Sadeghi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 87 3423 3331

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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**
Ayatalah Motahari Blvd, Resalat Square, Besat hospital
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## 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, accross the Mardom Park,Shahid Fahmideh Blvd
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**Email**
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 updating data

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student
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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**