

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Comparing the effectiveness and complications of Aspirin to Heparin and Enoxaparin in preventing venous thromboembolism in patients with fracture of extremities undergoing Open Reduction Internal Fixation (ORIF) surgery

#### Protocol summary

##### Study aim

Comparing the effectiveness and complications of Aspirin to Heparin and Enoxaparin in preventing venous thromboembolism in patients with fracture of extremities undergoing Open Reduction Internal Fixation (ORIF) surgery

##### Design

Three arm parallel group randomized single-blind trial

##### Settings and conduct

Trauma patients referred to Babol Shahid Beheshti teaching hospital with fracture of extremities undergoing ORIF surgery and receiving anticoagulants for venous thromboembolism prevention will enter the study. The study will be performed in the same center.

##### Participants/Inclusion and exclusion criteria

Trauma patients with fracture of extremities undergoing ORIF surgery and receiving anticoagulants for venous thromboembolism prevention will enter the study. Exclusion criteria are: hemorrhagic disorders, diseases that result in a hypercoagulable state, recent stroke, major surgery or trauma, myocardial infarction and uncontrolled hypertension during 3 months prior to surgery, gastrointestinal or urinary bleeding during the past 6 months, overt(known) renal or liver disease, use of NSAIDs during one week prior to surgery, allergy to heparin, active malignancy and pregnant women

##### Intervention groups

group 1: Aspirin 80mg tab. daily group 2: Enoxaparin 40mg amp. SQ daily group 3: Heparin 5000 IU amp. SQ BID (twice a day)

##### Main outcome variables

venous thromboembolism; complications of different anticoagulant regimens (ASA, Heparin, enoxaparin) given for VTE prophylaxis in patients with fracture of extremities who have undergone ORIF

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171223038021N1**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **retrospective**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

##### Registration date

2018-05-09, 1397/02/19

##### Registrant information

##### Name

Farbod Zahedi Tajrishi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3233 3103

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparing the effectiveness and complications of Aspirin to Heparin and Enoxaparin in preventing venous thromboembolism in patients with fracture of extremities undergoing Open Reduction Internal Fixation (ORIF) surgery

### Public title

Comparison of the effectiveness of anticoagulant protocols in orthopedic patients

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Trauma patients with initial diagnosis of extremity bone fracture who refer to Babol Shahid Beheshti Hospital in 2017-2018 and who undergo Open Reduction and Internal Fixation (ORIF) followed by receiving prophylactic anticoagulant therapy to prevent venous thromboembolism

#### Exclusion criteria:

hemorrhagic disorders diseases causing hypercoagulable state history of stroke recent major surgery or the need for one during current admission due to causes other than fracture history of recent major trauma other than the one that caused the fracture history of myocardial infarction uncontrolled hypertension during the past 3 months gastrointestinal and/or urinary bleeding during the past 6 months overt (known) liver and/or kidney disease NSAID use up to 1 week prior to surgery allergy to heparin active malignancy pregnant women

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: 150

### Randomization (investigator's opinion)

Randomized

### Randomization description

simple randomization using a random numbers table

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Participants in each of the 3 study groups (aspirin, enoxaparin and heparin) know they're being treated with one of these 3 drugs (for venous thromboembolism prophylaxis) but don't know which one exactly.

### Placebo

Not used

### Assignment

Parallel

### Other design features

The patients will be assigned randomly to 3 groups and will receive of these treatments accordingly for venous

thromboembolism prophylaxis: 1. Aspirin tab., 80 mg, daily; 2. Enoxaparin Amp., 40 mg, subcutaneous, daily; 3. Heparin Amp., 5000 IU, subcutaneous, daily

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences, Ganjafrooz Street

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶-۴۷۷۴۵

#### Approval date

2017-08-27, 1396/06/05

#### Ethics committee reference number

mubabol.hri.rec.1396.45

## Health conditions studied

### 1

#### Description of health condition studied

pulmonary embolism

#### ICD-10 code

I26

#### ICD-10 code description

Pulmonary embolism

### 2

#### Description of health condition studied

Deep vein thrombosis

#### ICD-10 code

I80.2

#### ICD-10 code description

Phlebitis and thrombophlebitis of other and unspecified deep vessels of lower extremities

### 3

#### Description of health condition studied

deep vein thrombosis

#### ICD-10 code

I80.1

#### ICD-10 code description

Phlebitis and thrombophlebitis of femoral vein

## Primary outcomes

### 1

#### **Description**

occurrence of pulmonary embolism in each venous thromboembolism prophylaxis method (including ASA, heparin and enoxaparin)

#### **Timepoint**

2 and 4 weeks after surgery

#### **Method of measurement**

Patients will be followed-up by the researcher. 2 and 4 weeks after surgery, patients will be re-evaluated with regards to any recent history of admission to hospital due to pulmonary embolism after the surgery. They will also be asked about the occurrence of symptoms such as acute unexplained dyspnea. A diagnosis of pulmonary embolism is definite when the patients presents any official hospital document with a confirmed diagnosis of pulmonary embolism or a when a combination of the mentioned symptoms and radiologic findings (such as a CT angiogram suggesting pulmonary embolism) are present.

### 2

#### **Description**

occurrence of deep vein thrombosis in each venous thromboembolism prophylaxis method (including ASA, heparin and enoxaparin)

#### **Timepoint**

2 and 4 weeks after surgery

#### **Method of measurement**

Patients will be followed-up by the researcher. 2 and 4 weeks after surgery, patients will be re-evaluated with regards to any recent history of admission to hospital due to deep vein thrombosis after the surgery. They will also be asked about the occurrence of symptoms such as cramps, pain, erythema, swelling or tenderness in the posterior portion of their legs that has not resolved spontaneously or have worsened through time. A diagnosis of deep vein thrombosis is definite when the patients presents any official hospital document with a confirmed diagnosis of the condition or a when a combination of the mentioned symptoms and radiologic findings (such as a doppler ultrasonogram of the veins of lower extremities suggesting deep vein thrombosis) are present.

## Secondary outcomes

### 1

#### **Description**

gastrointestinal bleeding

#### **Timepoint**

2 and 4 weeks after surgery

#### **Method of measurement**

asking the patients about any history of melena, bloody stool or vomiting blood after surgery

### 2

#### **Description**

hemorrhagic stroke

#### **Timepoint**

2 and 4 weeks after surgery

#### **Method of measurement**

asking the patients about any history of admission due to hemorrhagic stroke after surgery

### 3

#### **Description**

hemarthrosis

#### **Timepoint**

2 and 4 weeks after surgery

#### **Method of measurement**

history, physical exam and radiographic findings consistent with hemarthrosis

### 4

#### **Description**

allergic reaction to the assigned medication

#### **Timepoint**

2 and 4 weeks after surgery

#### **Method of measurement**

history and signs and symptoms consistent with allergic reaction to the medication used for venous thromboembolism prophylaxis

## Intervention groups

### 1

#### **Description**

Intervention group: Aspirin 80 mg tablet daily for 2 weeks after surgery

#### **Category**

Prevention

### 2

#### **Description**

Intervention group: Heparin 5000 IU Amp. twice daily, subcutaneous for 2 weeks after surgery

#### **Category**

Prevention

### 3

#### **Description**

Intervention group: Enoxaparin 40 mg Amp. daily, subcutaneous for 2 weeks after surgery

#### **Category**

Prevention

## Recruitment centers

### 1

#### **Recruitment center**

**Name of recruitment center**

Babol Shahid Beheshti Teaching Hospital

**Full name of responsible person**

Farbod Zahedi Tajrishi

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Rahmatollah Jokar

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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**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Farbod Zahedi Tajrishi

**Position**

medical intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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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)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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