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)

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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 hypergoagulable 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

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Babol

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Mazandaran

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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 aftrer 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

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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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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