# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 May 2026

## Comparison of intravenous enoxaparin with subcutaneous enoxaparin in preventing venous thromboembolism in patients admitted to intensive care unit

## Protocol summary


**Study aim**

Comparison of intravenous enoxaparin with subcutaneous enoxaparin in preventing venous thromboembolism in patients admitted to the intensive care unit

**Design**

This randomized clinical trial was performed on 20 patients in the intensive care unit. The patients were selected according to inclusion criteria and then randomly by using the draw. divided into groups receiving subcutaneous and intravenous enoxaparin.

**Settings and conduct**

The present randomized clinical trial was performed after approval by the Deputy of Research and Technology of Zahedan University of Medical Sciences and informed consent from legal guardians of the ICU patients admitted at Khatam-Al-Anbia Hospital in Zahedan (Iran).

**Participants/Inclusion and exclusion criteria**

Inclusion criteria were the age range of 18 -70 years, hospitalization for at least 48 hours in ICU, mechanical ventilation, normal renal and hepatic function, Exclusion Criteria: history of deep vein thrombosis and pulmonary embolism, history of coagulation disorders, treated with other anticoagulants before hospitalization, prosthetic implantation, myelodysplastic syndrome, and other blood dyscrasias, passing 48 hours from surgery in patients with intracerebral hemorrhage.

**Intervention groups**

Patients were divided into two groups: subcutaneous enoxaparin and intravenous enoxaparin. Subsequently, 2cc of the blood sample was taken of the patients in the two groups to measure the active factor Xa level. In the first group, 0.5 mg/kg of enoxaparin was injected subcutaneously. In the second group, the same dose of enoxaparin was injected slowly through a peripheral vein. Repeated blood sampling was done for measuring the factor level 4 hours after the first injection and 12 hours after the last injection on day 10, both groups were retested and the active factor Xa level was measured again.

**Main outcome variables**

Measure the active factor Xa level


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20191012045075N1**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**

**Registration date**

2020-01-26, 1398/11/06

**Registrant information**


**Name**

masoum khoshfetrat

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2013-09-23, 1392/07/01

**Expected recruitment end date**

2013-10-22, 1392/07/30

**Actual recruitment start date**
2013-09-23, 1392/07/01
**Actual recruitment end date**
2013-11-01, 1392/08/10
**Trial completion date**
2013-11-01, 1392/08/10

**Scientific title**
Comparison of intravenous enoxaparin with subcutaneous enoxaparin in preventing venous thromboembolism in patients admitted to intensive care unit

**Public title**
Comparison of intravenous enoxaparin with subcutaneous enoxaparin in preventing venous thromboembolism
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Ages 18 to 70 years Hospitalization for at least 48 hours in ICU Mechanical ventilation Normal renal and hepatic function Passing 48 hours from surgery in patients with intracerebral hemorrhage (epidural , subdural and intracerebral hematoma and hemorrhagic stroke)
**Exclusion criteria:**
History of deep vein thrombosis History of pulmonary embolism History of coagulation disorders (hemophilia, disseminated intravascular coagulation, idiopathic thrombocytopenia, heparin- induced thrombocytopenia and disruption of coagulation tests) Treated with other anticoagulants before hospitalization Prosthetic implantation (artificial heart valve, stent and IVC filter) Myelodysplastic syndrome and other blood dyscrasias
**Age**
From **18 years** old to **70 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **20**
Actual sample size reached: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The patients were selected by the convenience sampling method based on inclusion criteria, and then randomly divided into two groups. To ensure the randomization process, a total of 20 green and orange cards (corresponding to the estimated sample size) were prepared. A total of 10 green and 10 orange cards were assigned to each group, respectively the cards were arranged in the black box. After the patient having the inclusion criteria. A card was picked up from the box. And if the card was green, the patients assigned to the group I (subcutaneous enoxaparin). And if it was orange the patients assigned to group II(intravenous enoxaparin).
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Laboratory personnel who measured the patient's blood factor levels were unaware of the patients' placement in the study groups.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Zahedan University of Medical Sciences
**Street address**
Campus of Medical Sciences, Dr. Hassabi Square., University Ave., Zahedan Town
**City**
zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9861715799
**Approval date**
2013-07-28, 1392/05/06
**Ethics committee reference number**
IR.ZAUMS.REC.1392.6030

## Health conditions studied

### 1

**Description of health condition studied**
Intravenous thromboembolism
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Active factor Xa level
**Timepoint**
At baseline, 4 hours after the first injection, day 10 of the study 12 hours after the last injection
**Method of measurement**
The measurement of active factor levels was followed up by the laboratory without the researchers' knowledge of how the test was performed.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
In the first group, 0.5 mg/kg of enoxaparin (AVENTIS PHARMA Co., France) was injected subcutaneously in the deltoid region and rotationally the internal surface of the groin on both sides of the body.
**Category**
Treatment - Drugs

### 2

**Description**
In the second group, 0.5 mg/kg of enoxaparin (AVENTIS PHARMA Co., France) was injected slowly through a peripheral vein.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Khatam alanbia hospital
**Full name of responsible person**
Masoum khoshfetrat
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Zahedan University of Medical Sciences
**Full name of responsible person**
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University of Medical Sciences, Dr. Hasabi Square, University Street
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**Grant name**
Research budget
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Zahedan 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**
Zahedan University of Medical Sciences
**Full name of responsible person**
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**Position**
Associated Professor
**Latest degree**
Subspecialist
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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**
Not applicable

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
Not applicable

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable