Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 54 3324 5654

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khoshfetrat@zaums.ac.ir

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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Jame Jam Ave,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Masoum khoshfetrat
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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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