Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Subcutaneous and Intravenous Heparin Administration Methods for the Prevention of Venous Thromboembolism in the Intensive Care Unit

Protocol summary

Study aim

Comparison of subcutaneous and intravenous heparin injection methods (5000 units every 12 hours) on the prevention of venous thromboembolism and platelet changes in intensive care unit patients.

Design

A parallel-group, double-blind, randomized clinical trial with a 1:1 allocation ratio on 112 patients. Random Allocation Software was used for randomization.

Settings and conduct

The study will be conducted in the intensive care unit of Shahid Mohammadi Hospital, Bandar Abbas. After obtaining informed consent, 112 patients will be randomly assigned. Coagulation indices (PT, INR, aPTT) and platelet count will be recorded every 3 days. For signs suspicious of Venous Thromboembolism, Doppler ultrasound or CT angiography will be performed.

Participants/Inclusion and exclusion criteria

Patients admitted to the intensive care unit (ICU) of Shahid Mohammadi Hospital, Bandar Abbas, who were eligible for heparin prophylaxis (based on Wells or Caprini score ≥3 and no contraindications) were enrolled in the study. Exclusion criteria included allergy to heparin, severe thrombocytopenia (platelets <50,000), active bleeding, severe renal failure (CrCl <30 mL/min), lack of informed consent, and pregnancy.

Intervention groups

The first group received subcutaneous heparin (5000 units every 12 hours) and the second group received intravenous heparin (5000 units initial bolus + continuous infusion adjusted to maintain target aPTT). All patients received standard ICU care including hemodynamic monitoring, oxygen therapy, and basic VTE prophylaxis.

Main outcome variables

Primary outcome: occurrence of venous thromboembolism (Venous Thromboembolism) and changes in coagulation parameters (platelet count, PT, INR, aPTT). Secondary outcomes: incidence of major bleeding, thrombocytopenia, length of ICU stay, mortality, and lower limb size difference.

General information

Reason for update

Acronym

VTE

IRCT registration information

IRCT registration number: **IRCT20240929063203N4**
Registration date: **2025-12-20, 1404/09/29**
Registration timing: **prospective**

Last update: **2025-12-20, 1404/09/29**
Update count: **0**

Registration date

2025-12-20, 1404/09/29

Registrant information

Name

Milad Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 9999 4691

Email address

miladmohammadi981@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-25, 1404/10/04

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Subcutaneous and Intravenous Heparin Administration Methods for the Prevention of Venous Thromboembolism in the Intensive Care Unit

Public title
Comparison of Subcutaneous and Intravenous Heparin Administration Methods for the Prevention of Venous Thromboembolism in the Intensive Care Unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals aged 18 to 70 years Use of vasopressors Use of a central venous catheter Patients with platelet transfusions Patients with previous Venous Thromboembolism
Exclusion criteria:
Patients who develop heparin-induced thrombocytopenia (HIT) after starting treatment. Patients who experience bleeding at the surgical site or intracerebral bleeding (including epidural hematoma, subdural hematoma, intracerebral hemorrhage, and hemorrhagic stroke). Patients who require surgery for any reason; in these cases, heparin is discontinued 6 hours before surgery and the patient is excluded from the study.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
This clinical trial will use simple randomization with an individual randomization unit. Patients admitted to the intensive care unit (ICU) of Shahid Mohammadi Hospital, Bandar Abbas, who are eligible based on inclusion criteria (such as ICOPER criteria and no contraindication to heparin), will be allocated in a 1:1 ratio to two groups of subcutaneous heparin injection (5000 units/m2, twice daily) and intravenous heparin injection (5000 units/m2, twice daily). Random Allocation Software was used to generate the randomization sequence. Allocation concealment is ensured through segregation of responsibilities of the research team (separation of the enroller from the allocator), limited access control to the randomization sequence, and complete documentation of the process to minimize the possibility of selection bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind clinical trial in which patients, ICU attending physicians, nursing staff (except the injecting nurse), and outcome assessors (including the person performing the Doppler ultrasound, the clinical assessment of VTE symptoms, and the final judgment of VTE diagnosis) will be unaware of the prescribed heparin injection method (subcutaneous or intravenous) and patient allocation group. Preparation and administration of drugs will be performed by the injecting nurse who is not involved in the outcome assessment and clinical judgment. Heparin vials and syringes are provided with coded labels (A or B) without indicating the actual injection method. The allocation code will be kept in sealed envelopes and will not be opened until the end of the study and the completion of data analysis, except in emergencies. Data collection is performed by a research assistant or independent nurse who is unaware of patient allocation, and only the nurse responsible for preparing and administering the drug and the person responsible for randomization (who are not involved in enrollment and outcome assessment) will be aware of the allocation. This design minimizes the potential for performance bias and detection bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Hormozgan University of Medical Sciences
Street address
Shahid Chamran Boulevard
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2023-02-19, 1401/11/30
Ethics committee reference number
IR.HUMS.REC.1401.387

Health conditions studied

1

Description of health condition studied
Venous thromboembolism
ICD-10 code
180.1
ICD-10 code description
I80.1: Phlebitis and thrombophlebitis of femoral vein

Primary outcomes

1

Description
Occurrence of venous thromboembolism during intensive care unit hospitalization, based on clinical diagnosis and confirmed by imaging modalities (Doppler ultrasonography or computed tomography angiography).
Timepoint
From admission to discharge from the intensive care unit.
Method of measurement
Clinical assessment by the attending physician with diagnostic confirmation using Doppler ultrasonography or computed tomography angiography.

2

Description
Changes in platelet count.
Timepoint
Baseline (day 0), day 3, and day 7 of intensive care unit hospitalization.
Method of measurement
Laboratory measurement of platelet count using a venous blood sample; unit: ×1000/μL.

3

Description
Changes in prothrombin time.
Timepoint
Baseline (day 0), day 3, and day 7 of intensive care unit hospitalization.
Method of measurement
Laboratory measurement of prothrombin time using a venous blood sample; unit: seconds.

4

Description
Changes in international normalized ratio.
Timepoint
Baseline (day 0), day 3, and day 7 of intensive care unit hospitalization.
Method of measurement
Laboratory measurement of international normalized ratio using a venous blood sample; unitless.

5

Description
Changes in activated partial thromboplastin time.
Timepoint
Baseline (day 0), day 3, and day 7 of intensive care unit hospitalization.
Method of measurement
Laboratory measurement of activated partial thromboplastin time using a venous blood sample; unit: seconds.

Secondary outcomes

1

Description
Occurrence of major bleeding during intensive care unit hospitalization.
Timepoint
From admission to discharge from the intensive care unit
Method of measurement
Clinical evaluation by the attending physician and review of medical records based on standard criteria for major bleeding (including a decrease in hemoglobin level, need for blood transfusion, or bleeding at critical sites).

2

Description
Occurrence of thrombocytopenia.
Timepoint
Baseline (day 0), day 3, and day 7 of intensive care unit hospitalization.
Method of measurement
Laboratory measurement of platelet count using a venous blood sample; thrombocytopenia defined as a platelet count below the institutional reference range.

3

Description
Length of intensive care unit stay.
Timepoint
At discharge from the intensive care unit
Method of measurement
Calculation of the duration of intensive care unit hospitalization based on medical records; unit: days.

4

Description
Mortality.
Timepoint
From admission to discharge from the intensive care unit.
Method of measurement
Assessment of survival status through medical records during intensive care unit hospitalization.

5

Description

Difference in lower limb circumference.

Timepoint

Baseline (day 0), day 3, and day 7 of intensive care unit hospitalization.

Method of measurement

Measurement of lower limb circumference using a measuring tape at predefined anatomical landmarks; unit: centimeters.

Intervention groups

1

Description

Intervention group 1: Patients admitted to the ICU received 5000 units of non-fractionated heparin subcutaneously every 12 hours; the infusion began on the day of study entry and continued for at least 7 days or until discharge.

Category

Treatment - Drugs

2

Description

Second intervention group: Patients received unfractionated heparin with an initial bolus of 5000 intravenous units followed by continuous infusion (dose adjustment based on target aPTT of 1.5-2.5 times normal every 6 hours); duration similar to the first group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Great Prophet's (PBUH) Educational, Therapeutic, and Research Center.

Full name of responsible person

Pejman Shahrokhi

Street address

Shahid Mohammadi Hospital, Islamic Republic Blvd, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3333 3280

Fax

+98 76 3333 3280

Email

dr.pejman.shahrokhi@gmail.com

Web page address

https://shmh.hums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Shahram Zare

Street address

Shahid Mohammadi Hospital, Islamic Republic Blvd., Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 917 161 3924

Fax

+98 76 3333 3280

Email

shzare159@gmail.com

Web page address

https://hums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Majid Vatankhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Next to Recovery, 5-story Building, First Floor, Shahid Mohammadi Hospital, Islamic Republic Blvd., Bandar Abbas

City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3334 5009
Fax
Email
hormozgan91@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mehrdad Malekshoar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Next to Recovery, 5-story building, first floor, Shahid Mohammadi Hospital, Islamic Republic Blvd., Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3334 5009
Email
mdmalekshoar@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Milad Mohammadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Aila 2 Building, No. 3/9 Nour Alley, Emam Hossein Blvd, Nour Town
City
Bandar Abbas
Province
Hormozgan
Postal code
7919884206
Phone
+98 76 9999 4691
Fax
Email
miladmohammadi981@gmail.com

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
En Still undecided - no release schedule yet.
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