Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparing effects of low dose heparin as intermittent SC injection and continuous IV infusion on the serum biomarkers of thrombosis in critically ill patients

Protocol summary

Summary

The purpose of this study is comparing effects of different methods of heparin administration (intermittent SC injection and continuous IV infusion) on the serum biomarkers of thrombosis in critically ill patients. This study is a randomized, single-blind clinical trial. Forty six critically ill patients with indication for deep vein thrombosis prevention during ICU stay will be simply randomized in two equal groups. First group will be received SC heparin, 5000 IU three times a day for 7 days. The second group will be received heparin as continuous infusion with rate of 625 IU/hr for 7 days. Patients who need DVT or pulmonary emboli treatment, with heparin contraindications, autoimmune diseases, history of acute myocardial infarction and requiring dialysis will be excluded. Serum levels of the thrombosis biomarkers including P-selectin, Interleukin-10 and hs-CRP (C-reactive protein) will be measured at admission time and then days 3 and 7 in the included patients. Finally changes in the serum thrombosis biomarkers will be compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402113449N14**
Registration date: **2014-03-13, 1392/12/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-13, 1392/12/22

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-02-15, 1392/11/26

Expected recruitment end date

2016-02-15, 1394/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of low dose heparin as intermittent SC injection and continuous IV infusion on the serum biomarkers of thrombosis in critically ill patients

Public title

Heparin and deep vein thrombosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Critically ill patients with age between 18-65 years old who will be admitted to ICU and have indication for deep vein thrombosis (DVT) prophylaxis
Exclusion criteria: Patients who need DVT or pulmonary

emboli treatment, have heparin contraindications, autoimmune diseases, history of acute myocardial infarction in last 21 days, and dialysis.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Method of randomization: Based on the random number table Method of blinding: Patients and responsible person for data analysis will be blinded regarding type of intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Ghods Ave.

City
Tehran

Postal code

Approval date
2014-02-16, 1392/11/27

Ethics committee reference number
93-01-33-25173

Health conditions studied

1

Description of health condition studied
Deep vein throbmosis

ICD-10 code
I82

ICD-10 code description
Formation of thrombosis in the deep veins

Primary outcomes

1

Description
Incidence of deep vein thrombosis

Timepoint
Daily up to 7 days

Method of measurement
Clinical assessment

Secondary outcomes

1

Description
Interleukin-10 serum level

Timepoint
Days 0,3,7

Method of measurement
Elisa kit

2

Description
P-selectin serum level

Timepoint
Days 0,3,7

Method of measurement
Elisa kit

3

Description
hs-CRP serum level

Timepoint
Days 0,3,7

Method of measurement
Elisa kit

Intervention groups

1

Description
Subcutaneous (SC) heparin as 5000 IU TDS

Category
Treatment - Drugs

2

Description
Intravenous continuous infusion of heparin as 625 IU/hr

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Hossein Khalili

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Masoud Yunesian

Street address

Ghods Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Pharm. D

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty