Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the effect of heparinized normal saline flushing with prophylactic dose enoxaparin subcutaneous injection in the prevention of central venous catheter thrombosis in hospitalized high-risk patients

Protocol summary

Study aim

Determining effect of normal flushing of heparinized saline with subcutaneous injection of enoxaparin with a prophylactic dose in preventing central venous catheter thrombosis in high-risk patients admitted to Bahrami Hospital

Design

The current study is a phase 3 randomized clinical trial. Based on the determination of the sample size, 120 patients were included in the study and were divided into two equal groups using the Permuted Block Randomization method and the random table of numbers.

Settings and conduct

The study was conducted in the special care department of Bahrami Children's Hospital affiliated to Tehran University of Medical Sciences. Patients were divided into two equal groups of 60 people. After inserting the central venous catheter, the first intervention group included heparinized normal saline and the second intervention group received enoxaparin. At the beginning of the study, on the fourth day and one month after the study, the desired variables were measured.

Participants/Inclusion and exclusion criteria

The age of one month to 18 years; Patients with central venous catheter admitted to the intensive care unit; NO bleeding risk factors; Informed consent of the patient's parents or guardian to participate in study

Intervention groups

Group 1: Flushing 2 cc of heparinized normal saline every 8 hours after central venous catheter insertion. Group 2: Subcutaneous injection of enoxaparin 0.5 mg/kg every 12 hours after central venous catheter insertion.

Main outcome variables

Thrombosis; Sepsis; Heart beat; Body temperature; Respiratory rate; Hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230428058015N1**
Registration date: **2023-09-16, 1402/06/25**
Registration timing: **retrospective**

Last update: **2023-09-16, 1402/06/25**
Update count: **0**

Registration date

2023-09-16, 1402/06/25

Registrant information

Name

Maryam Mohebbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7754 7974

Email address

dr.m.mhb@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

2021-03-21, 1400/01/01

Actual recruitment end date

2022-03-21, 1401/01/01

Trial completion date

2022-08-23, 1401/06/01

Scientific title
Comparison of the effect of heparinized normal saline flushing with prophylactic dose enoxaparin subcutaneous injection in the prevention of central venous catheter thrombosis in hospitalized high-risk patients

Public title
Comparison of the effect of normal flushing of heparinized saline with subcutaneous injection of enoxaparin with a prophylactic dose in preventing central venous catheter thrombosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with central venous catheter admitted to the intensive care unit None of the bleeding risk factors Informed consent of the patient's parent or guardian to participate in the study Age one month to 18 years

Exclusion criteria:
Risk factors of central venous catheter thrombosis Anti-coagulant or anti-platelet medication use in the past 5 days Major surgery in the last 24 hours Glomerular filtration rate less than 30 Thrombocytopenia (platelets less than 50 thousand) Kidney, heart and liver disorders Uncontrolled blood pressure Lumbar puncture in the last 24 hours

Age
From **1 month** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients divided into two groups using Permuted Block Randomization. In this way, the two-block modes (AB, BA) are randomly assigned to each treatment order using a random number table and the placement of the two blocks.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Markazi Building, Qods St., Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2021-04-29, 1400/02/09

Ethics committee reference number
IR.TUMS.CHMC.REC.1400.239

Health conditions studied

1

Description of health condition studied
Vein thrombosis

ICD-10 code
I81

ICD-10 code description
Portal vein thrombosis

Primary outcomes

1

Description
Thrombosis

Timepoint
At the beginning of the study, 4 and 30 days after the intervention

Method of measurement
ultrasound

2

Description
Sepsis

Timepoint
At the beginning of the study, 4 and 30 days after the intervention

Method of measurement
Patient symptoms based on systemic inflammatory response syndrome

3

Description
Heart rate

Timepoint
At the beginning of the study, 4 and 30 days after the intervention

Method of measurement
Arterial pulse taking

4

Description
Body Tempretute
Timepoint
At the beginning of the study, 4 and 30 days after the intervention
Method of measurement
Thermometer

5

Description
Respiration rate
Timepoint
At the beginning of the study, 4 and 30 days after the intervention
Method of measurement
observation

6

Description
Hemoglobin
Timepoint
At the beginning of the study, 4 and 30 days after the intervention
Method of measurement
ELISA Kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Flushing 2 cc of heparinized normal saline with a concentration of 2 units of heparin per cc every 8 hours after central venous catheter insertion.
Category
Treatment - Drugs

2

Description
Intervention group: Subcutaneous injection of enoxaparin at a dose of 0.5 mg/kg every 12 hours after central venous catheter insertion.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami Pediatric Hospital
Full name of responsible person
Maryam Mohebbi
Street address
Bahrami Pediatric Hospital, Kiyaei St., Damavand St.
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7755 1584
Email
dr.m.mhb@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Mohebbi
Street address
Bahrami Pediatric Hospital, Kiyaei St., Damavand St.
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7756 8801
Email
dr.m.mhb@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Mohebbi
Position
Non-faculty specialist doctor

Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Bahrami Pediatric Hospital, Kiyaei St., Damavand St.
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7756 8801
Email
dr.m.mhb@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Mohebbi
Position
Non-faculty specialist doctor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Bahrami Pediatric Hospital, Kiyaei St., Damavand St.
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7756 8801
Email
dr.m.mhb@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Mohebbi
Position
Non-faculty specialist doctor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Bahrami Pediatric Hospital, Kiyaei St., Damavand St.
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7756 8801
Email
dr.m.mhb@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data is shared after unidentifiable people
When the data will become available and for how long
Start accessing 6 months after printing results
To whom data/document is available
It will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
For use in congress as a scientific document
From where data/document is obtainable
Dr. Maryam Mohebbi by email: dr.m.mhb@gmail.com
What processes are involved for a request to access data/document
As soon as the applicant requests to receive the documents, the data will be provided to them within two to three days email: dr.m.mhb@gmail.com
Comments