

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 Temperature

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.

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1641744991

Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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
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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences
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Latest degree
Specialist
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Person responsible for updating data

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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