

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intermediate dose of heparin solution in the prevention of central vein catheter occlusion on ICU admitted patients

Protocol summary

Study aim

Determining the effect of intermediate dose of heparin solution in the prevention of central vein catheter occlusion on ICU admitted patients admitted to intensive care unit

Design

A controlled clinical trial with parallel groups, double-blind, simple randomized, phase 3 will be performed on 153 patients. Random number table will be used in Excel software for randomization.

Settings and conduct

Patients who will be hospitalized in the intensive care unit of Imam Reza Hospital of Mashhad and will be have a central venous catheter implanted (less than 12 hours) will be entered in this study. In each patient, the lines will be divided into two categories: active or inactive. Blinding will be done using opaque, sealed and sealed envelopes.

Participants/Inclusion and exclusion criteria

Patients admitted to the intensive care unit with triceps central venous catheters, which are less than 12 hours after implantation and all its lines are functional, are included in the study. Exclusion criteria: patients who dialysis and freezing catheters and pulmonary artery catheters; implant ports; age less than 18 years old; pregnant women; heparin sensitivity; receive complete intravenous nutrition during the study period; active lines that need more than 3 times heparinization will be excluded.

Intervention groups

Active and Inactive lines in the intervention group are washed every 8 hours with 10 ml of saline solution and then locked with 1.5 ml of heparin solution (at a concentration of 100 units per ml).

Main outcome variables

Central vein catheter occlusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190905044704N1**

Registration date: **2021-08-19, 1400/05/28**

Registration timing: **prospective**

Last update: **2021-08-19, 1400/05/28**

Update count: **0**

Registration date

2021-08-19, 1400/05/28

Registrant information

Name

Asieh Yahyaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 3763

Email address

yahyaeia961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intermediate dose of heparin solution in the prevention of central vein catheter occlusion on ICU admitted patients		Name of ethics committee Ethics Committee of Mashhad University of Medical Science
Public title Effect of heparin in the prevention of central vein catheter		Street address Office off Research and Technology, Ghoreishi Building, Near Hoveize Cinema, Daneshgah Street
Purpose Prevention		City Mashhad
Inclusion/Exclusion criteria Inclusion criteria: All ICU admitted patients who had 3 functional lumen catheter that insert less than 12 hours Exclusion criteria: Dialysis and phresis and pulmonary artery catheters and insertable ports Age less than 18 y/o Pregnancy Heparin sensivity and HIT Coagolation system disorder and thrombocytopenia Therapeutic dose of anticoagolant Packed cell or any blood products transfusion TPN If the active lines needed more than 3 time heparization were excluded		Province Razavi Khorasan
Age From 18 years old		Postal code 9138813944
Gender Both		Approval date 2019-10-25, 1398/08/03
Phase 3		Ethics committee reference number IR.MUMS.MEDICAL.REC.1398.431
Groups that have been masked - Participant - Data analyser		Health conditions studied 1 Description of health condition studied Central vein catheters occlusion ICD-10 code T85 ICD-10 code description Complications of other internal prosthetic devices, implants and grafts
Sample size Target sample size: 150		Primary outcomes 1 Description Central vein catheter occlusion Timepoint Central vein catheters was checked every 8 hours untill 14 days Method of measurement Aspiration and infusion
Randomization (investigator's opinion) Randomized		Secondary outcomes empty
Randomization description Simple randomization in this way that Heparin and normal saline solution divided in number "one" and number "two" solution that nurse and patient do not know that and use this solution for patients with randomization.		Intervention groups 1 Description Intervention group: The active and inactive lines in the intervention group will be washed every 8 hours with 10 ml of saline solution and then locked with 1.5 ml of heparin solution at a concentration of 100 units per ml untill 14 days. Category Treatment - Drugs
Blinding (investigator's opinion) Double blinded		2 Description Control group: In the control group, only saline washing
Blinding description Heparin and normal salin solution divided in number one and number two solution that nurse and patient do not know that.		
Placebo Not used		
Assignment Parallel		
Other design features		
Secondary Ids empty		
Ethics committees 1 Ethics committee		

will be performed until 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Asieh Yahyaie

Street address

ICU C, second floor, Edalatian Department, Emam Reza Hospital, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 3763

Email

yahyaieia961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ahmad Bagheri Moghadam

Street address

ICU C, Second floor, Edalatian Department, Emam Reza Hospital

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Asieh Yahyaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

ICU C, second floor, Edalatian Department, Emam Reza Hospital, Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Asieh Yahyaie

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is shared after unidentifiable people

When the data will become available and for how long

6 months after publishing

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use data to compare with other similar interventions

From where data/document is obtainable

bagheria@mums.ac.ir

What processes are involved for a request to access data/document

email request

Comments