

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Compare the effect of heparin lock and normal saline flushing on central venous catheter patency in patients admitted to the intensive care unit

Protocol summary

Study aim

Comparison of central venous catheter opening time between flushing with normal saline and heparin lock in patients

Design

A randomized clinical trial of three groups with parallel groups and on 90 samples sorted using the site <https://www.random.org/integers>

Settings and conduct

This research is a clinical trial of three groups, the samples of which are hospitalized patients in the special care departments of Hashminejad and Imam Reza and Ghaem Hospitals in Mashhad. In patients whose central venous catheter has been in place for less than 24 hours, they are divided into three groups based on random allocation. In the first group, before clamping the duct, a solution of 30 units of heparin in a volume of 2 cc is injected into each duct and locked every 8 hours, and then the duct is clamped. 3 normal saline is washed every 8 hours. To check the openness of the central vein catheter, return without blood pressure into the syringe by aspirating with a 10cc syringe indicates that the catheter is open, and on the contrary, the duration of the catheter is recorded in hours. The duration of study for each group is 72 hours. After that, the researcher codes the data and enters SPSS software for analysis.

Participants/Inclusion and exclusion criteria

All hospitalized patients over 18 years of age hospitalized in the intensive care unit, less than 24 hours have passed since the placement of a three-channel central vein catheter in the subclavian region or internal jugular vein.

Intervention groups

1. the channel of the central venous catheter is locked with a concentration of 30 units of heparin 2.the channel of the central venous catheter is locked with a concentration of 50 units of heparin Control group: The catheter canal is washed with 10 cc of normal saline solutio

Main outcome variables

Catheter duct opening/closing The length of time the catheter duct remains open

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230228057559N1**

Registration date: **2023-03-07, 1401/12/16**

Registration timing: **prospective**

Last update: **2023-03-07, 1401/12/16**

Update count: **0**

Registration date

2023-03-07, 1401/12/16

Registrant information

Name

Elahe Saffari khozani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Compare the effect of heparin lock and normal saline flushing on central venous catheter patency in patients admitted to the intensive care unit

Public title
Compare the effect of heparin lock and normal saline flushing on central venous catheter patency in patients admitted to the intensive care unit

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All hospitalized patients over 18 years of age hospitalized in the intensive care unit who have a central venous catheter The patient's central venous catheter should be three ducts and the size of the catheter ducts should be 16, 18, 18. The patient is treated with anticoagulants Absence of obvious signs of infection at the catheter insertion site (discharge, redness, and swelling) Place the catheter in the subclavian or internal jugular vein The activated partial thromboplastin time (PTT) is within the normal range Less than 24 hours have passed since the central venous catheter was inserted At the beginning of the study, the site of catheter placement should be free of bleeding
Exclusion criteria:
Occurrence of infection symptoms at the catheter insertion site during the study Unwanted exit of the catheter from its anatomical location, for example, due to the patient's restlessness Bleeding at the catheter insertion site The patient needs cardiopulmonary resuscitation Occurrence of coagulation disorders and change of PTT outside the normal range

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The selection of the research samples is such that all the people hospitalized in special care units, who have the conditions to enter the study, are selected as the research sample. A table was prepared for the order of patients entering the study. At first, 30 numbers from one to three, 30 numbers from four to six, and 30 numbers from seven to nine were selected from

random.org/integers. Then, to randomize this list of 90 numbers, the part related to randomization of lists, website random.org/lists was used. In this way, the patients entering the study are assigned a random number that determines the relevant group. Numbers 1 to 3 are for the normal saline group (group A) and numbers 4 to 6 are grouped for the heparin group with a concentration of 30 units (group B) and numbers 7 to 9 are grouped for the heparin group with a concentration of 50 units (group C).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are not aware of their treatment method. Based on the drug preparation protocol, the researcher prepares the studied solutions and codes them as A, B, C. The interventionist (patient-specific nurse), without knowing the identity of these codes, injects solution A to patient A, and in the same way, the rest of the codes are also injected to the patient corresponding to their code. The evaluator (patient-specific nurse) records the opening of the catheter with the corresponding specific code in the patient-specific form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah Ave, Mashhad Town

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mashhad

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9138813944

Approval date

2023-01-03, 1401/10/13

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.101

Health conditions studied

1

Description of health condition studied

Mechanical complications of central venous catheter in intensive care unit patients

ICD-10 code

T82.5

ICD-10 code description

Mechanical complication of other cardiac and vascular devices and implants

Primary outcomes

1

Description

The duration of the opening of the central venous catheter

Timepoint

The primary outcome (catheter patency) is checked every 8 hours. The length of time the catheter remains is recorded at the end of the study or when the catheter is blocked

Method of measurement

How to set the duration of the central venous catheter open is the clock.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: In patients whose central venous catheter has been in place for less than 24 hours and who meet the conditions for entering the study, before clamping the central venous catheter, a solution of 30 units of heparin (Alborz Daru Company) in a volume of 2 cc every 8 hours inside Each duct is injected and locked, and then the duct is clamped. The central vein catheter channel is checked every 8 hours for the opening or blockage of the catheter by aspirating with a 10 cc syringe and observing the return of blood and fluids, as well as the presence of signs of infection and bleeding, and the result of the intervention is recorded.

Category

Prevention

2

Description

The second intervention group: In patients whose central venous catheter has been in place for less than 24 hours and who meet the conditions for entering the study, before clamping the central venous catheter, a solution of 50 units of heparin (Alborz Daru Company) in a volume of 2 cc every 8 hours inside Each duct is injected and locked, and then the duct is clamped. The central vein catheter channel is checked every 8 hours for the opening or blockage of the catheter by aspirating with a 10 cc syringe and observing the return of blood and fluids, as well as the presence of signs of infection and bleeding, and the result of the intervention is recorded

Category

Prevention

3

Description

Control group: In patients whose central venous catheter has been in place for less than 24 hours and who meet the conditions for entering the study, before clamping the central venous catheter, they are flushed with a volume of 10 cc of normal saline every 8 hours and then The conduit is clamped. The central vein catheter channel is checked every 8 hours for the opening or blockage of the catheter by aspirating with a 10 cc syringe and observing the return of blood and fluids, as well as the presence of signs of infection and bleeding, and the result of the intervention is recorded

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Hesam Sharifi Por Bahraman

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Imam Reza Square, Ibn Sina Street , Mashhad

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2

Recruitment center

Name of recruitment center

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3

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Elahe Saffari Khozani
Position
Nurse
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable