# 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**

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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

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Daneshgah Ave, Mashhad Town

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**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**

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## Sponsors / Funding sources

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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

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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