

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the preventive effect of gentamicin-lock and ethanol-lock in central venous catheter infection in children admitted to the pediatric intensive care unit.

#### Protocol summary

Prevention of infection (blood culture)

##### Study aim

Investigating the effect of lock therapy in reducing central venous catheter infection in patients admitted to the pediatric special care unit

##### Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2 on 228 patients. Randaize.com was used for randomization.

##### Settings and conduct

Patients are divided into three groups and in an interventional way, in one group ethanol, in one group gentamicin to smear the catheter path as lock therapy and in the third group, as a control group, no drug is used to smear the catheter path. Gentamicin with a volume of 0.25 cc (10 mg) is mixed with 9.75 cc of normal saline (ideally 1 mg in 1 cc) with a total volume of 10 cc. We inject the contents of the syringe of 5 cc of normal saline into the lumen and then aspirate. After the blood returns, the amount aspirated in the syringe is equivalent to the volume required to seal the lumen. Lock therapy is performed once a day in each line and continues for 7 days. In the case of ethanol, 70% alcohol is used. The volume of 0.2 cc is used to fill the lumen and remains in each lumen of the catheter for 4 hours, and during this time, the lumen must be unused. Before and after each lock therapy with ethanol, the line is washed with 5 to 10 cc of normal saline. Lock therapy is performed once a day in each line and continues for 7 days.

##### Participants/Inclusion and exclusion criteria

- Children between the ages of 1 month and 18 years admitted to the pediatric intensive care unit - Children who undergo central venous catheter implantation.

##### Intervention groups

Group 1: patients receiving ethanol as lock therapy.  
Group 2: patients receiving gentamicin as lock therapy.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221129056657N3**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

##### Registration date

2023-11-14, 1402/08/23

##### Registrant information

##### Name

Gholamreza khademi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3189 1780

##### Email address

khademigh@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-21, 1402/08/30

##### Expected recruitment end date

2024-11-20, 1403/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the preventive effect of gentamicin-lock and ethanol-lock in central venous catheter infection in children admitted to the pediatric intensive care unit.

**Public title**

Investigating the preventive effect of ethanol and gentamicin in central venous catheter infection

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Children between the ages of 1 month and 18 years admitted to the pediatric intensive care unit Children undergoing central venous catheter implantation

**Exclusion criteria:**

Hypersensitivity reaction to antibiotics or ethanol that is injected into the line. Any dysfunction of the line occurs after drug injection

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **228**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individual simple randomization Random number table randomization tool using www.randomization.com Allocation Concealment method: envelopes closed. In this method, first, a random sequence is created, then based on the size of the research sample, a number of envelopes with aluminum wrappers (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the generated random sequences is recorded on a card, and the cards are inside The letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

For blinding, statistical consultants and data analysts were unaware of the patient's randomization and placement in the therapy group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Committee on Ethics in Research, Faculty of Medicine, Mashhad University of Medical Sciences

**Street address**

Qurashi Building, Daneshgah Street, Mashhad.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177897157

**Approval date**

2023-09-23, 1402/07/01

**Ethics committee reference number**

IR.MUMS.REC.1402.178

**Health conditions studied****1****Description of health condition studied**

Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

**ICD-10 code**

T82.7

**ICD-10 code description**

Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

**Primary outcomes****1****Description**

Prevention of infection (blood culture)

**Timepoint**

Seven days after the start of the intervention

**Method of measurement**

Bactec automatic blood culture machine

**Secondary outcomes****1****Description**

Duration of stay in PICU

**Timepoint**

The time of discharge of the patient from the intensive care unit

## Method of measurement

Use of checklists and patient records

## Intervention groups

### 1

#### Description

Intervention group: Gentamicin with a volume of 0.25 cc (10 mg) is mixed with 9.75 cc of normal saline (ideally 1 mg in 1 cc) with a total volume of 10 cc. We inject the contents of the syringe of 5 cc of normal saline into the lumen and then aspirate. After the blood returns, the amount aspirated in the syringe is equivalent to the volume required to seal the lumen. Then that lumen is not used for 4 hours. Then the above volume is thrown away and varnish therapy is immediately performed in the other lumen. Two-lumen and three-lumen catheters will be used depending on the age and condition of the patient, and each lumen will be subjected to lock therapy separately and respectively. Lock therapy is performed once a day in each line and continues for 7 days.

#### Category

Prevention

### 2

#### Description

Intervention group: 70% alcohol is used. The volume of 0.2 cc is used to fill the lumen and remains in each lumen of the catheter for 4 hours, and during this time, the lumen must be unused. Two-lumen and three-lumen catheters are used depending on the age and condition of the patient. and each lumen will be subjected to lock therapy separately and in order. Before and after each lock therapy with ethanol, the line is washed with 5 to 10 cc of normal saline. Lock therapy is performed once a day in each line and continues for 7 days. From the time of catheter insertion, lock therapy starts and continues as prophylaxis, and the final result is evaluated after 7 days.

#### Category

Prevention

### 3

#### Description

Control group: As a control group, no drug is used to impregnate the catheter path.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbar Children's Hospital

##### Full name of responsible person

Gholamreza Khademi

##### Street address

Akbar Children's Hospital, Shahid Kaveh Boulevard

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177897157

##### Phone

+98 51 3871 3801

##### Fax

+98 51 3870 9201

##### Email

khademigh@mums.ac.ir

##### Web page address

<https://akbar.mums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

3rd floor, University Research and Technology Vice-Chancellor, University of Medical Sciences, University Street, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944 -91388

##### Phone

+98 51 3841 1538

##### Email

TafaghodiM@mums.ac.ir

#### 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**  
Gholamreza Khademi  
**Position**  
Associate Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Akbar Children's Hospital-Shahid Kaveh Boulevard -  
Mashhad  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177897157  
**Phone**  
+98 51 3189 1780  
**Fax**  
**Email**  
khademigh@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Khademi  
**Position**  
Associate Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Akbar Hospital, Shahid Kaveh Boulevard, Mashhad  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177897157  
**Phone**  
+98 51 3871 3801  
**Email**  
khademigh@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Khademi  
**Position**  
Associate Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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9177897157  
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khademigh@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not 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

No - There is not 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

Part of the data related to the main outcomes

### When the data will become available and for how long

Six months after the results are published

### To whom data/document is available

Academic institutions

### Under which criteria data/document could be used

For the purpose of research for the academic community

### From where data/document is obtainable

Dr. Gholamreza Khademi khademigh@mums.ac.ir

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

The request will be sent via email to Dr. Gholamreza Khademi and correspondence will be sent about two weeks after the registration of the data request.

### Comments