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

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. Randomaize.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

Prevention of infection (blood culture)

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
۹۱۷۷۸۹۷۱۵۷

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
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

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