Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of cefazolin-heparin lock therapy and ethanol-heparin lock therapy on the persistence and site infection in hemodialysis catheter patients

Protocol summary

Study aim
Comparison of the effectiveness of cefazolin-heparin lock and ethanol-heparin lock on the persistence and site infection catheters in hemodialysis patients

Design
This clinical trial with two intervention groups, double-blind, randomized, was performed on 80 patients.

Settings and conduct
This study is in the field of prevention of infection and increasing the shelf life of hemodialysis catheter. The study population consists of all hemodialysis patients with hemodialysis catheters. Blinding in this study includes a statistical evaluator and a nurse blocking solutions. Solutions in both study groups are blocked at the end of each hemodialysis session in patients' catheters. Until the next hemodialysis session, these solutions remain in the catheters. In the next hemodialysis, the patient is first evaluated for signs of infection. The blocked solution is then aspirated from the catheters and hemodialysis is started.

Participants/Inclusion and exclusion criteria
Informed consent Referral and introduction of the patient by the physician Age over 18 years

Intervention groups
ethanol-heparin lock group cefazoline-heparin lock group

Main outcome variables
-It is a cost-effective method compared to similar methods. -Reduce infection and increase catheter longevity. -Prevent wasting effective hemodialysis time and thus increase life expectancy in patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210811052145N1**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **retrospective**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date
2021-09-29, 1400/07/07

Registrant information

Name
Seyed mehdi Hosseinifard

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-08-13, 1400/05/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of cefazolin-heparin lock therapy and ethanol-heparin lock therapy on the persistence and site infection in hemodialysis catheter patients

Public title
Comparison of the effectiveness of cefazolin-heparin lock therapy and ethanol-heparin lock therapy on the persistence and site infection in hemodialysis catheter patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Referral and introduction of the patient by the physician over 18 years old
Exclusion criteria:
Lack of willingness to participate use of systemic antibiotics Use of immunosuppressive drugs Having a previous catheter or systemic infection
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple and individual random method was used. In this way, based on the sample size of the study and using the table of random number allocation, 80 codes from number one to eighty were assigned to patients (Randomized Allocation). Then the patients were randomly assigned to two intervention groups. ELT (Ethanol lock therapy) expression was considered for ethanol block group and ALT(Antibiotic lock therapy) expression was considered for cefazolin block group. Finally, after the researcher referred to the hemodialysis center, the eligible patients were assigned to two intervention groups based on the order of randomized codes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, nurses and statistical analysts are unaware of the type of block and groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of hormozgan University of Medical Sciences
Street address
Islamic Republic of Iran Blvd, shahid mohammadi hospital
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Bandar abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2019-05-29, 1398/03/08
Ethics committee reference number
052.۱۳۹۸.REC.HUMS.IR

Health conditions studied

1

Description of health condition studied
catheters site infection in hemodialysis pationts
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Prevention of catheter site infection
Timepoint
daily
Method of measurement
Redness - Sensitivity to touch - Hardening of catheter tissue about 2 cm - No fever or fever.

Secondary outcomes

1

Description
Increased catheter durability
Timepoint
daily
Method of measurement
From the time the catheter is inserted until the onset of symptoms of infection

Intervention groups

1

Description
ethanol-heparin block group: In the ethanol-heparin block group, participants received routine and standardized care after the end of the hemodialysis process, which included rinsing the catheter lumens with normal saline.

Finally, the ethanol-heparin block solution with a ratio of 2 (ethanol) to 1 (heparin) was blocked by a research colleague according to the volume of catheter lumens. It should be noted that the volume of the catheter lumens is about 3CC. The solution remains in the catheter until the next visit. At the next visit before hemodialysis, first evaluate the patient, including weight control and blood pressure by the researcher and complete the checklist for catheter infection according to the CDC criteria, which includes redness, tenderness, hardening of the catheter tissue about 2 cm, presence Or the absence of fever was done by the researcher and the ward manager. The blocked solution is then aspirated and hemodialysis is started.

Category

Prevention

2

Description

cefazolin lock group: In the cephazolin-heparin block group, after the end of the hemodialysis process, they received routine and standard care, which included rinsing the catheter lumens with normal saline, then cefazolin-heparin block solution with a ratio of 2 (cefazolin) to 1 (heparin). Was ready, Due to the lumen volume, the catheter was blocked by a research colleague. It should be noted that the volume of the catheter lumens is about 3CC. The solution remains in the catheter until the next visit. At the next visit before hemodialysis, the patient first evaluates the patient, including weight control and blood pressure, and completes a checklist for catheter infection according to the CDC criteria, which includes redness, tenderness, and hard The tissue of the catheter site is about 2 cm, the presence or absence of fever, was done by the researcher and the ward manager. Then the blocked solution is aspirated and hemodialysis is started. The solution remains in the catheter until the next visit. At the next visit before hemodialysis, first evaluate the patient, including weight control and blood pressure by the researcher and complete the checklist for catheter infection according to the CDC criteria, which includes redness, tenderness, hardening of the catheter tissue about 2 cm, presence Or the absence of fever was done by the researcher and the ward manager. The blocked solution is then aspirated and hemodialysis is started.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

dialysis Center of in Bandar Abbas

Full name of responsible person

Dr hadi yousefi

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

researcher

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

Master

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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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available