# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**
+98 38 3242 9362

**Email address**
mehdi.hoseinifard@yahoo.com

**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
**City**
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

**Street address**

Islamic Republic of Iran Boulevard

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Phone**

+98 38 3242 9362

**Email**

mehdi.hosseinifard@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Dr. Hadi Yousefi

**Street address**

Islamic Republic of Iran Boulevard

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Phone**

+98 38 3242 9362

**Email**

mehdi.hosseinifard@yahoo.com

**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**

Seyed Mehdi Hosseinifard

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery
**Street address**
No.14, 28Ave., Fadaeian Blvd., Farrokhshahr Town
**City**
Farrokhshahr
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8831855659
**Phone**
+98 38 3242 9362
**Fax**
**Email**
mehdi.hosseinifard@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Dr.Hadi Yousefi
**Position**
assistant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Epidemiology
**Street address**
Imam Hussain Boulevard
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7916613885
**Phone**
+98 76 3334 4429
**Email**
hadiyousefi17@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
mehdi hosseinifard
**Position**
student
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
No.14,28 Ave,fadieyan eslam Blvd,farrokh shahr Town
**City**
farrokh shahr
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8831855659
**Phone**
+98 38 3242 9362
**Email**
mehdi.hosseinifard@yahoo.com

## 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