Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The evaluation of efficacy of antibiotic lock accompanied by systemic antibiotic therapy in permanent haemodialysis by probability of catheter infection on the rate of infection of the catheter

Protocol summary

Study aim
Evaluation of the effect of using antibiotic locker simultaneously with systemic antibiotic treatment on increasing catheter retention in hemodialysis patients with the possibility of catheter infection

Design
Randomized clinical trial, with control group, with parallel groups, one-way blind, phase 3 on 60 patients. For randomization, the blocking method was performed with sealedenvelope.com online software and the sealed envelope concealment method was performed.

Settings and conduct
Sixty patients undergoing hemodialysis suspected of catheter infection referred to Amir Al-Momenin Hospital in Arak are randomly divided into control and intervention groups.The control group received standard treatment for catheter infection and premi-cath lock was routinely performed using heparin. The intervention group received standard treatment for catheter infection and permi-cath lock was performed using a hand-made solution containing antibiotics and heparin. Blinding is one-way blind and only patients are not aware of the study groups and patients' permi-cath will be lock in both groups using a colorless solution with equal volume.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Hemodialysis patients suspected of catheter infection, Exclusion criteria: Tunnel infection, concomitant infection, HIV positive, immunosuppression, intravenous drug addiction, severe sepsis

Intervention groups
Group A - patients who, in addition to systemic antibiotic therapy ،vancomycin and ceftazidime; Antibiotic lock of permi-cath lumens are made according to the solution making protocol in the design method. Group B - Patients who are routinely treated with systemic antibiotics vancomycin and ceftazidime through a peripheral vein and permi-cath lumens are routinely sealed with heparin alone.

Main outcome variables
Fever, length of hospital stay, leukocytosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210214050352N1**
Registration date: **2021-08-04, 1400/05/13**
Registration timing: **retrospective**

Last update: **2021-08-04, 1400/05/13**
Update count: **0**

Registration date
2021-08-04, 1400/05/13

Registrant information

Name
ahmad saebian

Name of organization / entity

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Iran (Islamic Republic of)

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+98 86 3417 3630

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ahmad.saebian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-05, 1399/12/15

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of efficacy of antibiotic lock accompanied by systemic antibiotic therapy in permanent haemodialysis by probability of catheter infection on the rate of infection of the catheter

Public title
The effect of antibiotic lock on catheter persistence in hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
End stage renal disease patients whose hemodialysis is performed using permi-cath and have a fever and have been hospitalized with a possible diagnosis of an infection catheter
Exclusion criteria:
Catheter Tunnel Infection Simultaneous infection of non-catheter origin HIV positive patients Intravenous drug users Immunodeficiency Severe sepsis
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups using block randomization method. In this way, before performing the disease, random block sequences will be created using the online software sealedenvelope.com and in 10 sequences of 6. The created sequences will then be placed in dark and sealed envelopes and the sequences will be numbered, respectively, and the disease will be treated using the created sequences, respectively.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was performed as a one-sided blind and the blinding will be done in such a way that the participating patients are not aware of the study groups and the type of their intervention and the participating groups are known only by letters (A and B). The clinical caregiver and the facilitator are aware of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Payambar-e-azam Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2021-05-30, 1400/03/09
Ethics committee reference number
IR.ARAKMU.REC.1400.043

Health conditions studied

1

Description of health condition studied
Permi-cath infection
ICD-10 code
T80.21
ICD-10 code description
Infection due to central venous catheter

Primary outcomes

1

Description
Fever
Timepoint
Every 8 hours
Method of measurement
Mercury Therommeter

2

Description
Leukocytosis
Timepoint
Daily
Method of measurement
Blood cell counter

Secondary outcomes

1

Description
Duration of hospitalization

Timepoint
When discharged from the hospital
Method of measurement
Based on hospitalization file

Intervention groups

1

Description
Intervention group: 30 patients for whom standard systemic antibiotic therapy of vancomycin 7.5mg / kg as stat and ceftazidime 2 gr as stat after each dialysis will be performed by peripheral intravenous injection and antibiotic lock of permi-cath lumens will be performed by using 2 ml of hand solution Colorless instrument for each lumen, including 5 mg / ml vancomycin (Elixir-Iran), 10 mg / ml ceftazidime (Elixir-Iran) and 10000 IU / ml heparin (Pharmacopoeia-Iran), after each dialysis and until blood culture results are ready.
Category
Treatment - Drugs

2

Description
Control group: 30 patients for whom standard systemic antibiotic therapy of vancomycin 7.5mg / kg as stat and ceftazidime 2 gr as stat after each dialysis will be performed by peripheral intravenous injection and lock of permi-cath lumen will be performed by using 2 ml of solution containing 10000IU / ml of heparin (Darupakhsh-Iran), after each dialysis and until blood culture results are ready.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-al-momenin hospital
Full name of responsible person
Ahmad Saebian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Ahmad Saebian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
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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
Undecided - It is not yet known if there will be a plan to make this available