

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 premi-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' premi-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 premi-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 premi-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

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3630

Email address

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

Street address

Amir-al-momenin hospital, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3601

Email

it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3645

Email

research@arakmu.ac.ir

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

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3645

Email

Ahmad.saebian@yahoo.com

Person responsible for scientific 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

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3645

Email

Ahmad.saebian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ahmad Saebian

Position

Resident

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Infectious diseases

Street address

Payambar azam Complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3630

Fax

+98 86 3417 3630

Email

Ahmad.saebian@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

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