

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

To evaluate the effect of single dose prophylactic vancomycin before semi-permanent catheterization to prevent catheter related infection: Randomized Controlled Trial, Phase 2

Protocol summary

Study aim

Determining the rate of reduction of infection with vancomycin before semi-permanent catheterization in 1399 in Golestan Hospital

Design

The study was performed as a randomized double-blind clinical trial based on a random number table. Patients with chronic renal failure admitted to the nephrology ward of Ahvaz Golestan Hospital who need dialysis and hemodialysis dual catheter installation are examined.

Settings and conduct

The study was conducted as a randomized double-blind clinical trial based on a random number table. Patients with chronic renal failure admitted to the nephrology ward of Ahvaz Golestan Hospital who require dialysis and installation of a double-sided hemodialysis catheter are examined. The intervention group receives one gram of vancomycin antibiotic by intravenous injection one hour before catheterization. The control group receives normal saline in the same volume by a person who is not aware of the research. The patient and the people evaluating the final outcomes have no knowledge of grouping the people into the intervention and control groups.

Participants/Inclusion and exclusion criteria

- Patient with ESRD - Not using antibiotics before the study
- Sterile conditions during catheter installation
- Lack of evidence of infection in other parts of the body
- Satisfaction to participate in the study

Intervention groups

To evaluate the effect of vancomycin antibiotic before semi-permanent catheterization to prevent catheter-dependent infection, the intervention group received one gram of vancomycin antibiotic by intravenous injection and normal saline with the same volume one hour before catheterization.

Main outcome variables

The main outcome variables in this study included reviewing and comparing the incidence of catheter related infection over a period of 6 months; The time of the catheter related infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201206049617N1**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name

Zohreh Zandbaf

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

farajzadeh_h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To evaluate the effect of single dose prophylactic vancomycin before semi-permanent catheterization to prevent catheter related infection: Randomized Controlled Trial, Phase 2

Public title
To evaluate the effect of single dose prophylactic vancomycin before semi-permanent catheterization to prevent catheter related infection: Randomized Controlled Trial, Phase 2

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
patient with ESRD Not using antibiotics before the study
sterile conditions during catheter installation
Lack of evidence of infection in other parts of the body
Satisfaction to participate in the study
Exclusion criteria:
No end-stage renal disease or no need to install a catheter for dialysis

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly divided into two groups based on the method of 4 random block permutations. The site sealedenvelope.com Randomization section under Create a List section was used to generate a randomization sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, physicians, nurses, data collectors, those assessing the consequences, and the Safety and Data Monitoring Committee were kept blind. In order to eliminate the bias caused by the knowledge of them, the results are based on the type of treatment received and its possible impact on the research result of the study in a double-blind manner. Similar vials were used for vancomycin and placebo, and randomization was

performed by sealedenvelope.com, according to which each patient was placed in the treatment or control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jondishapur Medical Sciences

Street address

Ahvaz Jondishapur Medical Sciences, Golestan Ave

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-11-21, 1399/09/01

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.106

Health conditions studied

1

Description of health condition studied

Catheter related infection

ICD-10 code

T82.7XXA

ICD-10 code description

Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter

Primary outcomes

1

Description

Incidence of catheter-dependent infection

Timepoint

6 months

Method of measurement

Blood culture, Catheter lumen culture and signs of infection including fever and purulent discharge from the catheter site

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with end-stage renal disease receive one gram of the vancomycin antibiotic by intravenous injection one hour before the implantation of a semi-permanent catheter.

Category

Prevention

2

Description

Control group: Patients with end-stage renal disease receive normal saline by intravenous injection one hour before catheterization.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Meyssam Moezzi

Street address

Golestan Hospital, Golestan ave

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golestanjpspital@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Zohreh Zandbaf

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Zohreh Zandbaf

Position

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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
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Zohreh Zandbaf
Position
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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