

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

Khuzestan

##### 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

Meysam Moezzi

#### Street address

Golestan Hospital, Golestan ave

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135733118

#### Phone

+98 61 3374 3001

#### Email

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

#### Street address

Ahvaz Jondishapur University of Medical Sciences,  
Golestan Ave

#### City

Ahvaz

### Province

Khouzestan

### Postal code

6135715794

### Phone

+98 61 3336 2414

### Email

itc@ajums.ac.ir

### 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

#### Street address

Golestan Hospital, Golestan ave

#### City

Ahvaz

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#### Phone

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farajzadeh\_h@ajums.ac.ir

## Person responsible for scientific 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**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Zohreh Zandbaf  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
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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