

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparative study of the effect of Heparin alone or in combination with Amikacin and Vancomycin antibiotics in the prevention of infection caused by tunnel central catheters in patients with renal insufficiency undergoing hemodialysis

Protocol summary

Study aim

Comparison of the effect of heparin alone or in combination with vancomycin and amikacin antibiotics topically in the prevention of infection caused by tunnel central catheters in patients with renal failure undergoing hemodialysis

Design

Clinical trial with parallel, double-blind, randomized groups based on random number table, phase 2 on 60 patients with end-stage renal disease undergoing hemodialysis with tunnel central catheter

Settings and conduct

60 patients with end-stage renal failure who are undergoing chronic hemodialysis with a central tunneled catheter are divided into two groups A and B. Double-blinding will be performed, so that the patient and the researcher responsible for data entry will be unaware of the intervention performed. For groups A and B, respectively, heparin alone and heparin in combination with vancomycin and amikacin were used locally, and during a six-month follow-up, the rate of infection caused by the catheter will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: End-stage renal failure patients undergoing chronic hemodialysis with a tunneled central catheter. Exclusion criteria: Antibiotic use in the previous two weeks.

Intervention groups

Intervention group: Heparin (5000 units/ml) plus Vancomycin (500 mg) and local Amikacin (500 mg) antibiotics in the catheter lumen; Control group: Heparin (5000 units/ml) in the catheter lumen

Main outcome variables

Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210317050735N1**

Registration date: **2023-01-04, 1401/10/14**

Registration timing: **prospective**

Last update: **2023-01-04, 1401/10/14**

Update count: **0**

Registration date

2023-01-04, 1401/10/14

Registrant information

Name

MARYAM IRANIKIA

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 2886

Email address

dr.maryam.1983@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Assignment Parallel
Scientific title Comparative study of the effect of Heparin alone or in combination with Amikacin and Vancomycin antibiotics in the prevention of infection caused by tunnel central catheters in patients with renal insufficiency undergoing hemodialysis	Other design features
Public title Evaluation of the effect of Heparin alone and in combination with Vancomycin and Amikabisen in the prevention of tunnel catheter infection	Secondary Ids empty
Purpose Prevention	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Insertion of a new central tunnel catheter for hemodialysis Absence of inflammation in the vascular access area at the beginning of the study At least 2 months after starting dialysis Perform 2 or 3 dialysis sessions per week Being over 18 years old No specific diseases such as Leukemia, Infection, Immunodeficiency, Dermatitis Exclusion criteria: Having an infectious disease in other parts of the body Antibiotic use in the previous two weeks	1 Ethics committee Name of ethics committee Ethics Committee of Ardabil University of Medical Sciences Street address Fatemi hospital, Imam Khomeini street City Ardabil Province Ardabil Postal code ۵۶۱۴۷۳۳۷۷۵
Age From 18 years old	Approval date 2021-04-17, 1400/01/28
Gender Both	Ethics committee reference number IR.ARUMS.REC.1399.632
Phase 2	Health conditions studied
Groups that have been masked - Participant - Care provider	1 Description of health condition studied End stage renal disease ICD-10 code N18.6 ICD-10 code description End stage renal disease
Sample size Target sample size: 60 More than 1 sample in each individual Number of samples in each individual: 3 Blood samples from arterial and venous lines of catheter and peripheral blood for each person	Primary outcomes
Randomization (investigator's opinion) Randomized	1 Description Incidence of catheter-related infections in patients under hemodialysis Timepoint Six-month follow-up of the two groups Method of measurement Blood culture to evaluate for catheter-related infection
Randomization description Random numbers table is used for randomization. In order to use random numbers table, it will be determined first to read the numbers in the table, then the numbers are considered for different groups. We put our hands on one of the numbers and move in one of the predetermined directions and assign the numbers to different groups.	Secondary outcomes
Blinding (investigator's opinion) Double blinded	1 Description Fever Timepoint During the 6-month follow-up period Method of measurement
Blinding description The study will be blinded bilaterally. Patients will be blinded to the type of intervention and the researcher who must enter the data into the relevant checklist will be blinded to the type of intervention.	
Placebo Not used	

fever measurement

Intervention groups

1

Description

Intervention group A: Patients undergoing hemodialysis who have recently had a tunneled central venous catheter installed will enter group A after obtaining consent. In this group, at the beginning of each dialysis session, 5000 units of heparin (manufactured by Caspin Pharmaceuticals) are injected into each lumen of the catheter, and the patients are evaluated for the occurrence of infection for six months.

Category

Treatment - Drugs

2

Description

Intervention group B: Patients undergoing hemodialysis who have recently had a tunneled central venous catheter installed will enter group B after obtaining consent. In this group, at the beginning of each dialysis session, 5 mg of vancomycin (manufactured by Dana Pharmaceuticals) and 5 mg of amikacin (manufactured by Caspin Pharmaceuticals) plus 5000 units of heparin are injected into each catheter lumen, and the patients are evaluated for the occurrence of infection for six months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi hospital

Full name of responsible person

Maryam Iranikia

Street address

Fatemi hospital, Imam Khomeini street

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Phone

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Email

Dr.maryam.1983@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mohammadreza Aslani

Street address

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Ardabil

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Dr_maryam1983@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Maryam Iranikia

Position

Resident of general surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

No 26, Molavi st, Shahid hamzezadeh st, Hafez ave

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Individual data from study participants included demographic information, medical history, and evidence of catheter-related infection

When the data will become available and for how long

Access starts six months after the results are published

To whom data/document is available

Researchers working in academic and medical centers , physicians and medical students

Under which criteria data/document could be used

For reference in conducting similar studies by mentioning the original source

From where data/document is obtainable

Ardabil University of Medical Sciences, Vice Chancellor for Research or email Dr_maryam1983@gmail.com

What processes are involved for a request to access data/document

Contact by email or refer to the Vice Chancellor for Research of Ardabil University of Medical Sciences and make a request, full explanation of the purpose of having the data, provide a guarantee to mention the source

Comments

Person responsible for updating data

Contact

Name of organization / entity

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