

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of Preventive Protocol for Central Venous Catheter-Related Infection (Antibiotic Lock Therapy and TauroLock) in Hemodialysis Patients.

Protocol summary

Study aim

Evaluation of the effect of Antibiotic Lock and Troulak in preventing catheter infection in hemodialysis patients

Design

This evaluation is a clinical trial in phase 3, hemodialysis patients with catheters are considered as a study group. In this study, 86 patients who meet the inclusion criteria are selected. Patients are randomly assigned and blocked by two categories. 43 patients are in the Troulak group and 43 patients are in the Antibiotic lock group. Accordingly, after the end of each month, the rate of catheter infection in them is compared.

Settings and conduct

Site of Study: Imam Hossein Hospital, Tehran
Methods: This study is performed on two groups of hemodialysis patients in a three-blind manner. One group receives Troulak and the other group receives antibiotic lock. At the end of each month, blood culture will be prepared from the catheter of the patients.

Participants/Inclusion and exclusion criteria

Entry criteria for study: All the ESRD dialysis patients through permacath who Present informed consent for attending in the study. Non-entry criteria: Patients who have past history of IV drug abusing; past history of active systemic infections before permacath insertion; changing the catheter to AV fistula; past surgical history within the last year and past history of allergy to antibiotics are not allowed in study.

Intervention groups

Tauroloc or Tarolidin citrate group that causes reduction in the rate of infection compared to heparin use.
Antibiotic lock group, which its effectiveness is under study.

Main outcome variables

Side effects from the treatment protocol Such as the possibility of drug resistance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210921052544N1**

Registration date: **2022-05-01, 1401/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-01, 1401/02/11**

Update count: **0**

Registration date

2022-05-01, 1401/02/11

Registrant information

Name

Maryam Delgosha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Preventive Protocol for Central Venous Catheter-Related Infection (Antibiotic Lock Therapy and TauroLock) in Hemodialysis Patients.

Public title

Evaluation of Preventive Protocol for Central Venous Catheter-Related Infection (Antibiotic Lock Therapy and TauroLock) in Hemodialysis Patients.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All End Stage Renal Disease patients dialysis through permacath Presenting informed consent for attending in study

Exclusion criteria:

Poor blood flow during dialysis Past history of IV drug abusing Past history of active systemic infections before permacath insertion Change the catheter to AV fistula Past surgical history within the last year Past history of allergies to antibiotics

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The case-study patients are randomized into two groups. The allocation of patients in the two groups had been based on demographic characteristics and their assimilation. Accordingly, after the patients were divided into two equal groups in terms of number based on demographic information, we included the patients in the study and performed the desired intervention on them. In this study, taurolock- manufactured by Tauropharm GmbH Company- and the combination of vancomycin with heparin- manufactured by Exir Pharmaceutical Company- are visually numbered in similar ampoules and only the person in charge of the study knows the contents. The drugs are distributed in the dialysis center. Neither of nurse in charge and the patient know about the type of solution. Each patient is assigned an ID sheet contained the patient's details and the number of the solution of the received drug. Patients receive the solution randomly each time they are being on dialysis. The randomization method is simple and the randomization unit is the person who numbers the used ampoules in the random number table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this way, patients in the two groups, analyzer and outcome assessor, do not know about the drug used and the packaging of drugs is done in the same way

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital -Shahid Arabi Street -Yemen Street - Shahid Chamran highway - Tehran

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2021-03-06, 1399/12/16

Ethics committee reference number

IR.SBMU.MSP.REC.1399.753

Health conditions studied**1****Description of health condition studied**

Catheter infection

ICD-10 code

T80.211A

ICD-10 code description

Bloodstream infection due to central venous catheter, initial encounter

2**Description of health condition studied**

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

The rate of catheter infection in hemodialysis patients

Timepoint

Checking blood culture from catheter lines and peripheral blood at the end of each month

Method of measurement

Culture of catheter lines and peripheral blood

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one(Taurolock manufactured by TauroPharm GmbH Company): At the end of each dialysis, the patient's premcath lines are filled with taurolock and each month blood culture sample is prepare from the patient's premcath lines.Also blood culture sample is prepared from peripheral blood and permacath in the case of symptoms of infection.

Category

Prevention

2

Description

Intervention group two(Antibiotic lock-combination of vancomycin and heparin manufactured by Exir Pharmaceutical Company):At the end of each dialysis, the patient's premcath lines are filled with antibiotic lock and each month blood culture sample is prepare from the patient's premcath lines.Also blood culture sample is prepared from peripheral blood and permacath in the case of symptoms of infection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam hussein hospital

Full name of responsible person

Nasiri Amirahmad

Street address

Imam Hussein hospital - Shaidd Madani Ave - Imam Hussein square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Velenjak streer , Shahid Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Delgosha

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Nassiri Amirahmmad

Position

Associate professor

Latest degree

Subspecialist

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Person responsible for updating data

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Internal medicine Resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information will be published as a result of the analysis.

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