# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

+98 21 2256 7826

**Email address**

mary.delgosha@gmail.com

**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 whitin 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**
Hemodyalisis

**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 - Shaid Madani Ave - Imam Husseine square

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

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**Full name of responsible person**

Afshin Zarghi

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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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## Person responsible for updating data

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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