# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluation of the efficacy or inefficacy of TauroLock in the prevention of catheter-related infection and thrombosis in hemodialysis patients

### Protocol summary

**Study aim**
Evaluating the effectiveness or lack of effectiveness of TauroLock in preventing catheter-related infection and thrombosis in hemodialysis patients.

**Design**
A randomized double-blind clinical trial with two intervention groups on 60 patients

**Settings and conduct**
After meeting the conditions for entering the study, the patients are randomized using a table of random numbers, and by placing them in one of the intervention groups, their basic and clinical information is recorded at the beginning, during the study, and at the end.The resulting consequences are evaluated Place of study: Hemodialysis department of hospitals in Yazd province

**Participants/Inclusion and exclusion criteria**
Patients over 18 years of age need to receive hemodialysis through a central venous catheter three times a week and patient's informed consent are main conditions for entering the study.

**Intervention groups**
In the first group, TauroLock™-HEP500 is used as a catheter lock solution at the end of each hemodialysis session. In the second group, unfractionated heparin with a concentration of 5000 i.u/mL is used as a catheter lock solution at the end of each hemodialysis

**Main outcome variables**
Prevention of catheter-related infection and thrombosis in patients undergoing hemodialysis and increasing life expectancy in patients as a result

### General information

**Reason for update**
The email address of the person responsible for scientific accountability has been corrected

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240821062823N1**
Registration date: **2024-09-05, 1403/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-07, 1403/07/16**
Update count: **1**

**Registration date**
2024-09-05, 1403/06/15

**Registrant information**

**Name**
Atefe Dehghan Mongabadi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-08-26, 1403/06/05

**Expected recruitment end date**
2024-12-05, 1403/09/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the efficacy or inefficacy of TauroLock in the prevention of catheter-related infection and thrombosis in hemodialysis patients

**Public title**
Effect of TauroLock in prevention of catheter-related

infection

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients more than 18 years old who need hemodialysis by central venous catheters 3 times a week informed patient consent

**Exclusion criteria:**

History of thrombocytopenia following heparin administration Lack of informed consent of the patient

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At the time of entering the study, patients are randomized into one of the two intervention groups using a table of random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the participants and the main researcher and the outcome assessor are unaware of the allocation of the study groups and performing direct therapeutic interventions based on the study design method is the responsibility of the clinical caregivers of the health center.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of the faculty of medicine, Shahid Sadougi University of Medical Sciences,Yazd

**Street address**

Faculty of pharmacy,Shohadaye Gomnam Blvd, Alam Square, Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

8915173149

**Approval date**

2024-07-08, 1403/04/18

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1403.084

## Health conditions studied

### 1

**Description of health condition studied**

Catheter-related infection

**ICD-10 code**

T80.21

**ICD-10 code description**

Infection due to central venous catheter

### 2

**Description of health condition studied**

Central venous catheter line thrombosis

**ICD-10 code**

T82.868

**ICD-10 code description**

Thrombosis of vascular prosthetic devices, implants and grafts

## Primary outcomes

### 1

**Description**

Catheter-related infection

**Timepoint**

At the beginning and end of the study and if there are signs of infection during the study

**Method of measurement**

Culture from catheter sample and peripheral blood sample

### 2

**Description**

catheter thrombosis

**Timepoint**

At the beginning and end of the study and if catheter ineffectiveness observed during the study

**Method of measurement**

Observation of catheter thrombosis and complications in successful dialysis in full time period during routine dialysis sessions

## Secondary outcomes

### 1

**Description**

Dialysis efficiency

**Timepoint**
At the beginning and end of the study
**Method of measurement**
calculating Urea Reduction Ratio ( URR ) and Kt/V

## Intervention groups

### 1

**Description**
Intervention group: At the end of each dialysis session during a month, the patient's CVC lines are flushed with Taurolock-hep500, and at any time during the study, in case of signs of infection, a blood culture is prepared from the patient's peripheral blood and catheter.
**Category**
Prevention

### 2

**Description**
Intervention group: At the end of each dialysis session during a month, the patient's CVC lines are flushed with unfractionated Heparin 5000 i.u/ml , and at any time during the study, in case of signs of infection, a blood culture is prepared from the patient's peripheral blood and catheter.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Rahnemoun Hospital
**Full name of responsible person**
Dr Mehdi Zahmatkesh
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Farrokhi Street, Yazd
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Yazd University of Medical Sciences
**Full name of responsible person**
Dr Fatemeh Saghafi Abarghouei
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Shohadaye Gomnam Blvd, Alam Square ,Yazd
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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**
Yazd 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**
Yazd University of Medical Sciences
**Full name of responsible person**
Dr Fatemeh Saghafi Abarghouei
**Position**
Associate Professor of Clinical Pharmacy
**Latest degree**
Specialist
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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)**
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