

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3828 9366

###### Email address

atefe.dehghan78@yahoo.com

##### 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 Gornam 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

##### Street address

Farrokhi Street, Yazd

##### City

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##### Province

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##### Phone

+98 35 3312 3010

##### Email

rahnamoon@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Dr Fatemeh Saghafi Abarghouei

##### Street address

Shohadaye Gomnam Blvd, Alam Square ,Yazd

##### City

yazd

##### Province

Yazd

##### Postal code

8915173149

##### Phone

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##### Email

info@ssu.ac.ir

#### 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

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Shohadaye Gomnam Blvd, Alam Square, Yazd

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

**Full name of responsible person**

Dr Mehdi Zahmatkesh

**Position**

Assistant Professor of Nephrology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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

**Person responsible for updating data****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

**Other areas of specialty/work**

Medical Pharmacy