

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 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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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

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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

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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

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Associate Professor of Clinical Pharmacy

Latest degree

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Other areas of specialty/work

Medical Pharmacy