

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of heparin, reteplase and taurolock in the prevention of thrombosis in hemodialysis catheters

Protocol summary

Study aim

Comparison of the effect of heparin, reteplase and taurolock in the prevention of thrombosis in hemodialysis catheters

Design

Clinical trial - with one control group and five intervention groups - parallel groups - sample size of 35 people in each group (185 people in total) - consecutive non-probability sampling method - three-way blind - randomized

Settings and conduct

The present study is a clinical trial in which the effect of three drugs, heparin, rateplase and taurolack, on the prevention of thrombosis in a hemodialysis catheter (premixt) is investigated. The sample size is 37 people in each group, which includes four intervention groups and one control group, and is performed in a three-sided manner. Fifty units), in the third group Taurolock (five mg), in the fourth group reteplase (one mg) and in the control group according to the routine heparin (five thousand units) that the rate of catheter occlusion due to thrombosis up to six months after intervention Are considered and reviewed

Participants/Inclusion and exclusion criteria

Entry requirements : Dialysis patients with catheter (permcath) Patient satisfaction No entry conditions: No permcath catheter for dialysis Mentioning the history of allergies to the intervened drugs Lack of awareness to obtain satisfaction

Intervention groups

Dialysis patients have a hemodialysis catheter (premixt) which is assigned to four intervention groups and a control group. In one group high-dose heparin (one thousand units), in the second group low-dose heparin (fifty units), In the third group, they receive taurolock(five mg), in the fourth group, reteplase (one mg) and in the control group, they receive heparin (five thousand units) according to the routine.

Main outcome variables

Hemodialysis catheter thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220103053614N1**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

Registration date

2022-01-30, 1400/11/10

Registrant information

Name

azadeh razian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3323 6402

Email address

azadeh.r697@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-09, 1400/08/18

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of heparin, reteplase and taurolock in the prevention of thrombosis in hemodialysis catheters

Public title
Comparison of the effect of heparin, reteplase and taurolock in the prevention of thrombosis in hemodialysis catheters

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Dialysis patients with catheter (premixt) Patient satisfaction
Exclusion criteria:
No premix catheter for dialysis Mentioning the history of allergies to the intervened drugs Lack of awareness to obtain satisfaction

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **185**

Randomization (investigator's opinion)
Randomized

Randomization description
. Despite the contingency of non-consecutive sampling, the samples are assigned in groups randomly. For assigning patients to 5 groups (four intervention groups and one control group), the stratified random allocation method is used. The classes are made based on the patient's age, patient's gender and duration of dialysis (8 classes in total). Within each floor, patients are assigned to groups using the method of random permutation blocks (five blocks) and with the tool of random number table.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patient, the thrombus evaluator and the statistical analyst do not know the type of intervention performed on the patient. It should be noted that neither the thrombus assessor nor the decoder are members of the research team.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Kia building, Valiasr alley, Maharat boulevard, 60 meters boulevard,

City

khorrabad

Province

Lorestan

Postal code

6814983906

Approval date

2021-11-08, 1400/08/17

Ethics committee reference number

IR.LUMS.REC.1400.206

Health conditions studied

1

Description of health condition studied

Thrombosis in dialysis catheters

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Thrombosis in dialysis catheters

Timepoint

At the beginning of the study and six months after the intervention

Method of measurement

Successful full dialysis during routine dialysis sessions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of high dose heparin (1000 units) plus 2 cc of distilled water to the number of dialysis patients per week in both lines of hemodialysis catheter

Category

Treatment - Drugs

2

Description

Intervention group: Low dose heparin injection (50 units) plus 2 cc of distilled water to the number of dialysis patients per week in both lines of hemodialysis catheter

Category

Treatment - Drugs

3

Description

Intervention group: Injection of Taurolack ampoule 5 mg plus 2 cc of distilled water to the number of dialysis patients per week in both lines of hemodialysis catheter

Category

Treatment - Drugs

4

Description

Intervention group: Injection of Reteplase 1 mg plus 2 cc of distilled water to the number of dialysis patients per week in both lines of hemodialysis catheter

Category

Treatment - Drugs

5

Description

Control group: Heparin according to the patient's routine (5,000 units) plus 2 cc of distilled water in each catheter line the number of times dialysis per week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Ashayer and Shahid Rahimi Hospital in khorramabad

Full name of responsible person

Azadeh razian

Street address

Enghelab Street, at the beginning of the Street of the shohadaye ashayer Hospital

City

khorramabad

Province

Lorestan

Postal code

6819843757

Phone

+98 66 3323 6401

Email

azadeh.r.697@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ebrahim Falahi

Street address

Moallem St., Shahid Anoushirvan Rezaei Square

City

khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

publicrelation@lums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

azadeh razian

Position

General Surgery Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Kia building, Valiasr alley, Maharat boulevard, 60 meters boulevard

City

khorramabad

Province

Lorestan

Postal code

6817362060

Phone
+98 66 3324 3965
Email
azadeh.r697@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
azadeh razian
Position
General Surgery Assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Kia building, Valiasr alley, Maharat boulevard, 60 meters boulevard
City
khorramabad
Province
Lorestan
Postal code
6817362060
Phone
+98 66 3324 3965
Email
azadeh.r697@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
azadeh razian
Position

General Surgery Assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Kia building, Valiasr alley, Maharat boulevard, 60 meters boulevard,
City
khorramabad
Province
Lorestan
Postal code
6817362060
Phone
+98 66 3324 3965
Email
azadeh.r697@yahoo.com

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