Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (premict) 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 (premict) 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 (premict) 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
khorramabad

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
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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
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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
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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