Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effectiveness of Reteplase and Heparin ampoules in patients with permicate catheter dysfunction undergoing hemodialysis

Protocol summary

Study aim

Determination and comparison of the efficacy of Reteplase injection versus Heparin injection in patients with dysfunctional Permcath catheters undergoing hemodialysis

Design

A clinical trial with a control group, parallel arms, phase 3, on 63 patients.

Settings and conduct

After patient allocation into two groups (intervention with rtPA and control with Heparin), the Permcath catheter will be flushed according to the study protocol. Catheter function will be assessed in each hemodialysis session based on adequate blood flow, acceptable venous pressure and absence of clinical signs of occlusion. The number of effective catheter function days will be calculated from the day of flushing until recurrent occlusion or the end of follow-up. The number of successful hemodialysis sessions will also be recorded during the follow-up period

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient aged 18 years older undergoing hemodialysis via a central venous catheter (CVC) that have become obstructed or dysfunctional Exclusion criteria: Presence of active infection at the catheter site, Contraindications to Heparin or Reteplase, such as active bleeding or severe thrombocytopenia, Patients requiring catheter removal for reasons other than obstruction such as severe infection or catheter displacement

Intervention groups

Intervention group: Flushing with Reteplase injection at a dose of 1 mg per catheter lumen, administered intraluminally, and retaining the solution for at least 30 minutes before normal saline flushing. Control group: Flushing with Heparin injection at the standard concentration of 5000 units/ml per catheter lumen, administered intraluminally, and retaining the solution for at least 30 minutes before normal saline flushing.

Main outcome variables

Number of effective catheter function days and number of successful hemodialysis sessions after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260226068952N1**
Registration date: **2026-03-18, 1404/12/27**
Registration timing: **prospective**

Last update: **2026-03-18, 1404/12/27**
Update count: **0**

Registration date

2026-03-18, 1404/12/27

Registrant information

Name

Soroor Abd Emami

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3333 6001

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Studying the effectiveness of Reteplase and Heparin ampoules in patients with permicate catheter dysfunction undergoing hemodialysis

Public title
Studying the effectiveness of Reteplase and Heparin ampoules in patients with permicate catheter dysfunction undergoing hemodialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient aged 18 years older undergoing hemodialysis via a central venous catheter (CVC) Implanted Permcath catheters that have become obstructed or dysfunctional Provision of written informed consent to participate in the study

Exclusion criteria:
Presence of active infection at the catheter site Contraindications to Heparin or Reteplase, such as active bleeding or severe thrombocytopenia Patients requiring catheter removal for reasons other than obstruction such as severe infection or catheter displacement Withdrawal of consent or discontinuation by the patient

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Sub-1, Mavedat Alley, Shahid Beheshti Blvd.,

City
Qazvin

Province
Qazvin

Postal code
3414443936

Approval date
2026-02-24, 1404/12/05

Ethics committee reference number
IR.QUMS.REC.1404.443

Health conditions studied

1

Description of health condition studied
Dysfunction of Permcath catheter in patients undergoing hemodialysis

ICD-10 code
T82.898

ICD-10 code description
Other specified complication of vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description
Number of effective catheter function days and number of successful hemodialysis sessions after intervention: After patient allocation into two groups (intervention with rtPA and control with Heparin), the Permcath catheter will be flushed according to the study protocol. Catheter function will be assessed in each hemodialysis session based on adequate blood flow (>200 ml/min), acceptable venous pressure (>250 mmHg) and absence of clinical signs of occlusion. The number of effective catheter function days will be calculated from the day of flushing until recurrent occlusion or the end of follow-up (minimum 3 to 6 months). The number of successful hemodialysis sessions (sessions performed with adequate blood flow and without the need for additional intervention) will also be recorded during the follow-up period.

Timepoint
At each hemodialysis session, from the day of intervention until catheter re-occlusion or end of follow-up (3 to 6 months).

Method of measurement
All data will be collected and documented by trained nurses and physicians using standardized case report forms.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Flushing with Reteplase injection at a dose of 1 mg per catheter lumen, administered intraluminally, and retaining the solution for at least 30 minutes before normal saline flushing.
Category
Treatment - Drugs

2

Description
Control group: Flushing with Heparin injection at the standard concentration of 5000 units/ml per catheter lumen, administered intraluminally, and retaining the solution for at least 30 minutes before normal saline flushing.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Soroor Abd Emami
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22 Bahman Blvd., Elahieh St., Minoudar Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyed Mehdi Mirhashemi
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Sub-1, Mavedat Alley, Shahid Beheshti Blvd.,
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3415613911
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research.dpt@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Soroor Abd Emami
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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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