

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

Email address

s.abdeemami@gmail.com

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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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