Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

An evaluation of the effectiveness of taurolidine, 30% citrate, 4% citrate, and heparin as lock solutions in preventing infections among patients with end-stage renal disease (ESRD) requiring dialysis

Protocol summary

Study aim

Comparative Efficacy of Taurolidine, 30% Citrate, 4% Citrate, and Heparin Lock Solutions in Preventing Catheter-Related Infections in Hemodialysis Patients with Central Venous Catheters

Design

A phase 3 randomized (using a number table) double-blind trial allocated 276 patients into three intervention groups and one control group.

Settings and conduct

Patients will be divided into four groups: three intervention groups receiving taurolidine, 4% citrate, or 30% citrate lock solutions, and a control group receiving heparin according to the standard protocol of Imam Hossein, Qaem, Shohada Ghamnam, and Shariati hospitals. Lock solutions will be administered immediately after each dialysis session, with blood samples collected every 14 days for culture, CBC, differential, CRP, and procalcitonin. All patients will be followed for three months.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • 18<age<80 .Hemodialysis >2 sessions/week. . Catheterization >3 months or prior catheter removal >12 months before trial enrollment. Exclusion Criteria: • Use of systemic antibiotics within 14 days prior to enrollment • catheter-site infection •]mmunodeficiency • Pregnancy or lactation • Allergy to citrate, heparin, or taurolidine • History of seizures

Intervention groups

Patients were randomized into four groups (n=69 each). Three intervention groups received taurolidine, 4% citrate, or 30% citrate lock solutions, while the control group received heparin according to hospital protocol. The assigned lock solution was administered after each dialysis session.

Main outcome variables

Incidence of catheter-related bloodstream infections (CRBSI), Number of catheter-related infections per group, Catheter patency and survival, Adverse events related to lock solutions, Laboratory parameter changes, Frequency of catheter replacements, Occurrence of systemic or secondary infections.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250503065575N1**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date

2025-10-07, 1404/07/15

Registrant information

Name

Kosar Ojaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 499 0816

Email address

kosarojaghi@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2028-03-19, 1406/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
An evaluation of the effectiveness of taurolidine, 30% citrate, 4% citrate, and heparin as lock solutions in preventing infections among patients with end-stage renal disease (ESRD) requiring dialysis

Public title
An evaluation of the effectiveness of taurolidine, 30% citrate, 4% citrate, and heparin as lock solutions in preventing infections among patients with end-stage renal disease (ESRD) requiring dialysis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Dialysis patients aged 18 to 80 years Catheterization >14 days or prior catheter removal >3 months before trial enrollment. Hemodialysis > 2 sessions/ week
Exclusion criteria:
Antibiotic use within 14 days prior to enrollment. Active infection at the site of the catheter Immunodeficiency pregnant woman Breastfeeding Allergy to Citrate, Heparin and Taurolidine History of seizure Any disease with vasculopathy
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **276**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will first be selected according to the study's inclusion and exclusion criteria. Following the provision of informed consent, individuals will be randomly allocated to either the intervention or control group using appropriate randomization methods (e.g., random number tables). This randomization aims to ensure a balanced distribution of both known and unknown confounding factors across groups, with each participant having an equal probability of assignment to either arm. In this study, group allocation will be managed by an independent individual, not involved in the research team, to minimize selection and allocation bias. For this purpose, a sufficient number of sealed, opaque envelopes will be prepared for the intervention and control groups, with the assigned group (intervention or control) concealed inside each envelope. Data will be collected and analyzed without knowledge of group assignments. Whenever feasible, the intervention and placebo will be designed to have an identical appearance, and both participants and outcome assessors will remain blinded to group allocation (double-blind design). Upon completion of data collection, the allocation code will be unsealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In a double-blind study, blinding the patient involves preparing the active treatment and placebo to look, smell, and be administered in exactly the same way, so the patient cannot distinguish between them. To blind the healthcare staff, treatment packages are labeled with codes or identification numbers, and only an independent party (such as a pharmacist or randomization officer) who is not involved in the trial has access to the group assignments. Researchers and outcome assessors also work with coded data and remain unaware of the actual group allocations until the data collection is complete. This process prevents both conscious and unconscious influence on treatment administration or outcome evaluation, ensuring the scientific validity of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti medical science university
Street address
Shahid Beheshti medical science university, Daneshjoo blvd
City
Tehran
Province
Tehran
Postal code
193954631
Approval date
2025-04-29, 1404/02/09
Ethics committee reference number
IR.SBMU.MSP.REC.1404.073

Health conditions studied

1

Description of health condition studied
Catheter infections in patients undergoing dialysis
ICD-10 code
T82.7
ICD-10 code description
Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

2

Description of health condition studied
End stage renal disease
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

3

Description of health condition studied
Dependence on renal dialysis
ICD-10 code
T82.7
ICD-10 code description
Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts

Primary outcomes

1

Description
Incidence of Catheter-Related Bloodstream Infections (CRBSIs)
Timepoint
Every 14 days
Method of measurement
Blood culture and laboratory parameters

Secondary outcomes

1

Description
White blood cell
Timepoint
Every 14 days
Method of measurement
Blood sample

2

Description
Temprature
Timepoint
Every 14 days
Method of measurement
Thermometer

3

Description
Heart rate
Timepoint
Every 14 days
Method of measurement
Heart monitoring

4

Description
C-reactive protein
Timepoint
Every 14 days
Method of measurement
Blood sample

5

Description
Procalcitonin
Timepoint
Every 14 days
Method of measurement
Blood sample

Intervention groups

1

Description
Control group: Heparin at a concentration of 1,000–5,000 units/mL will be instilled into the catheter lumen as a lock solution after each hemodialysis session. This regimen represents the standard practice routinely employed in the hospital.
Category
Prevention

2

Description
first Intervention group: Taurolidine will be instilled into the catheter lumen as a lock solution after each hemodialysis session, in a volume corresponding to the internal volume of the lumen.
Category
Prevention

3

Description
second Intervention group: citrate 4% will be instilled into the catheter lumen as a lock solution after each hemodialysis session, in a volume corresponding to the internal volume of the lumen.
Category
Prevention

4

Description

Intervention group: Citrate 30% will be instilled into the catheter lumen as a lock solution after each hemodialysis session, in a volume corresponding to the internal volume of the lumen.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam hossein hospital

Full name of responsible person
Behzad azimi

Street address
Imam hossein hospital, Madani st., Imam hossein sq.

City
Tehran

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 3000

Email
info@sbmu.ac.ir

2

Recruitment center

Name of recruitment center
Shohadaye Gomnam hospital

Full name of responsible person
Amir ahmad nasiri

Street address
15 meters from the Shohadaye Gomnam, Aref Intersection, Khavaran Street

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tehran

Province
Tehran

Postal code
1794694616

Phone
+98 21 3631 2001

Email
hospital@sbmu.ac.ir

3

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Amir Ahmad nasiri

Street address
in front of the Faculty of Economics, Jalal Al Ahmad intersection, North Kargar St.

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Shahid beheshti university of medical science

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1983969411

Phone
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Email
info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
kosar ojaghi

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Kosar Ojaghi
Position
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Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
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Person responsible for updating data

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Other areas of specialty/work
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Tehran
Postal code
1617763141
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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
No - There is not 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