Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Hemostatic effectiveness of intranasal desmopressin for tunneled dialysis catheter placement

Protocol summary

Study aim

This study aims to determine the effectiveness of intranasal desmopressin in reducing the risk of bleeding after insertion of tunneled dialysis catheters.

Design

Two arm parallel group randomised trial without blinding

Settings and conduct

This study would be conducted on patients with end stage renal disease requiring tunneled dialysis catheters for haemodialysis. Patients would be selected using consecutive sampling from the dialysis unit. All of them would be asked to give consent. Patients would be randomized into 2 groups using sequences generated online (and concealed as described above). Patients in the intervention arm would receive intranasal desmopressin, 1 puff in each nostril, 30 minutes before the procedure. This step would be omitted in the control group. Tunneled dialysis catheters would be inserted in the Dialysis Unit Procedure Room under ultrasound guidance. Fluoroscopic guidance is not available, and would thus not be used. All catheters would be inserted using Seldinger technique. Patients would be observed in the hospital for 24 hours after the procedure to record bleeding from exit site.

Participants/Inclusion and exclusion criteria

We will include patients of either gender, aged 12 years or more, who require placement of tunneled dialysis catheters for maintenance haemodialysis. Exclusion criteria include uncontrolled blood pressure (>180/110 mmHg), previous catheter placement at the same time, coagulopathy, current use of anticoagulants and platelets count <50,000.ul.

Intervention groups

Patients in the intervention arm would receive intranasal desmopressin. This would be a single dose of 1 puff in each nostril administered 30 minutes before the catheter placement.

Main outcome variables

Primary outcome would be bleeding from the exit site.

Secondary outcome would be the requirement of some intervention (chiefly purse string suture) in case of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240215061017N2**
Registration date: **2025-02-12, 1403/11/24**
Registration timing: **prospective**

Last update: **2025-02-12, 1403/11/24**
Update count: **0**

Registration date

2025-02-12, 1403/11/24

Registrant information

Name
Abdul Rehman Arshad
Name of organization / entity
National University of Medical Sciences
Country
Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-25, 1403/12/07

Expected recruitment end date

2025-10-25, 1404/08/03

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Hemostatic effectiveness of intranasal desmopressin for tunneled dialysis catheter placement

Public title
Usefulness of desmopressin in reducing bleeding during insertion of tunneled dialysis catheters
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
End stage renal disease requiring insertion of tunneled dialysis catheter
Exclusion criteria:
Current use of anticoagulants Platelets count <50,000/µl Previous tunneled dialysis line insertions at the same site Blood pressure >180/110 mmHg Unwillingness
Age
From **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Individual patients would be randomized into two groups using sequences generated online before the patient enrollment gets started. This randomization list will be kept with the Principal Investigator. All doctors performing the catheter insertion procedures would contact him personally to check which arm each successive patient is to be randomized to.
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
Research Review Board, Combined Military Hospital Lahore
Street address
Abdul Rehman Road, Lahore Cantonment
City
Lahore
Postal code
54810
Approval date
2025-02-06, 1403/11/18
Ethics committee reference number
603/2025

Health conditions studied

1

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

Primary outcomes

1

Description
Bleeding from the catheter exit site
Timepoint
Within 24 hours of the intervention
Method of measurement
Visual inspection and reporting by the patients

Secondary outcomes

1

Description
Need for intervention to control bleeding from catheter exit site
Timepoint
Within 24 hours of the interventon
Method of measurement
Review of medical records

2

Description
New onset headache (side effect)
Timepoint
Within 24 hours of intervention
Method of measurement
Direct inquiry from the patient

Intervention groups

1

Description
Intervention group: Patients in this group would be given

a single puff of desmopressin in each nostril, 30 minutes before the insertion of tunneled dialysis catheters. After half an hour, catheters would be inserted in such patients.

Category
Treatment - Drugs

2

Description
Control group: Patients in this group will not receive any intervention. Catheters would be inserted straight away.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Combined Military Hospital Lahore

Full name of responsible person
Abdul Rehman Arshad

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Abdur Rehman Road, Lahore Cantt

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
CMH Lahore Medical College

Full name of responsible person
Abdul Rehman Arshad

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Grant name

Grant code / Reference number

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

Title of funding source
CMH Lahore Medical College

Proportion provided by this source
100

Public or private sector
Private

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
CMH Lahore Medical College

Full name of responsible person
Abdul Rehman Arshad

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Nephrology

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Person responsible for scientific inquiries

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Internal Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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

Title and more details about the data/document
Individual patient data would be shared on Harvard Dataverse once the study is published in a biomedical journal

When the data will become available and for how long
After publication of paper in a biomedical journal

To whom data/document is available
For anyone who may be interested

Under which criteria data/document could be used
No restrictions

From where data/document is obtainable
By emailing the PI

What processes are involved for a request to access data/document
Request forwarded by email

Comments