

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Phone

+92 345 6746747

Email address

maj.abdulrehman@gmail.com

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/ μ l
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 intervention

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

CMH Lahore Medical College

Full name of responsible person

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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**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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