

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of purse string suture in preventing bleeding after insertion of tunneled haemodialysis catheters

Protocol summary

Study aim

Assessing the validity of purse-string suturing as an effective modification in TDL placement procedure by comparing incidence of bleeding in patients with and without purse-string suturing

Design

Two arm parallel group randomised trial with outcome assessment without blinding

Settings and conduct

This trial would be conducted at Department of Nephrology, Pak Emirates Military Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients of either gender aged 18 years or greater, requiring venous access for maintenance hemodialysis. Exclusion Criteria: Acute kidney injury, bleeding disorders other than uremic platelet dysfunction, blood pressure $\geq 180/110$ mmHg, current use of anticoagulants, platelet count $< 50,000/\mu\text{l}$, deranged prothrombin time / activated partial thromboplastin time, non-cooperative patient. previous tunneled catheter insertions at the same site

Intervention groups

Patients in this group would receive a purse string suture approximately one centimeter above the catheter exit site on the upper chest

Main outcome variables

Incidence of bleeding after insertion of tunneled hemodialysis catheter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250101064242N1**

Registration date: **2025-01-14, 1403/10/25**

Registration timing: **retrospective**

Last update: **2025-01-14, 1403/10/25**

Update count: **0**

Registration date

2025-01-14, 1403/10/25

Registrant information

Name

Obaid Ur Rahman

Name of organization / entity

National University of Medical Sciences Pakistan

Country

Pakistan

Phone

+92 336 5025270

Email address

obaid.96@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-04, 1402/02/14

Expected recruitment end date

2023-10-16, 1402/07/24

Actual recruitment start date

2023-05-04, 1402/02/14

Actual recruitment end date

2023-10-23, 1402/08/01

Trial completion date

empty

Scientific title

Effectiveness of purse string suture in preventing bleeding after insertion of tunneled haemodialysis catheters

Public title

Exit site suture after insertion of tunneled haemodialysis catheters

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Requirement of venous access for maintenance hemodialysis.

Exclusion criteria:

Acute kidney injury blood pressure >180/110 mmHg current use of anticoagulants bleeding disorders other than uremic platelet dysfunction platelet count < 50,000/ μ l deranged prothrombin time / activated partial thromboplastin time non-cooperative patient previous tunneled catheter insertions at the same site

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Actual sample size reached: **138**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomized in to two groups using online computer generated sequences. These sequences were concealed in opaque envelopes to ensure concealment.

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

Ethical Committee of Pak Emirates Military Hospital

Street address

The Mall Road

City

RAWALPINDI

Postal code

46000

Approval date

2023-04-27, 1402/02/07

Ethics committee reference number

A/28/ERC/200/24

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 exit site

Timepoint

Within 24 hours of catheter insertion

Method of measurement

Reporting to paramedical staff by patients or their caregivers

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients in this group would have a purse string suture applied one centimeter from the exit site at the end of the procedure.

Category

Treatment - Surgery

2

Description

Control group: All patients in this group would not have any purse string suture applied at the end of the procedure.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital

Full name of responsible person

Obaid-Ur-Rahman

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

Pak Emirates Military Hospital

Full name of responsible person

Sohail Sabir

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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

Pak Emirates Military Hospital

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**

Pak Emirates Military Hospital

Full name of responsible person

Obaid Ur Rehman

Position

Registrar

Latest degree

Bachelor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Pak Emirates Military Hospital

Full name of responsible person

Obaid Ur Rahman

Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Effectiveness of purse string suture in preventing bleeding after insertion of tunneled haemodialysis catheters

When the data will become available and for how long

For one year after publication of the paper

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Free to use

From where data/document is obtainable

By contacting the first author

What processes are involved for a request to access data/document

By approaching via email

Comments