Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≥180/110 mmHg, current use of anticoagulants, platelet count < 50,000/µl, 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/µl 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

Street address

The Mall Road

City

Rawalpindi

Postal code

46000

Phone

+92 336 5025270

Email
obaid.96@hotmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Sohail Sabir
Street address
The Mall Road
City
Rawalpindi
Postal code
46000
Phone
+92 336 5025270
Email
obaid.96@hotmail.com
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
Street address
The Mall Road
City
Rawalpindi
Province
Punjab
Postal code
46000
Phone
+92 336 5025270
Email
obaid.96@hotmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Obaid Ur Rahman
Position
Registrar
Latest degree
Bachelor
Other areas of specialty/work
Internal Medicine
Street address
The Mall Road
City
Rawalpindi
Province
Punjab
Postal code
46000
Phone
+92 336 5025270
Email
obaid.96@hotmail.com

Person responsible for updating data

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
Street address
The Mall Road
City
Rawalpindi
Province
Punjab
Postal code
46000
Phone
+92 336 5025270
Email
obaid.96@hotmail.com

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