Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of Half Dose and One Third Dose of Injection Taurolock® for Tunneled Double Lumen Catheter Lock Solution

Protocol summary

Study aim

To compare the efficacy of TaurolockHEP500®, as half and one third of standard dose on prevention of catheter related blood stream infection and catheter dysfunction in patients undergoing hemodialysis via tunneled double lumen catheter.

Design

Two arm parallel group randomized trial, phase N/A, sample size of 314 , two centers

Settings and conduct

Randomized controlled study was conducted at Armed Forces Institute of Urology Rawalpindi and Pak Emirates Military Hospital Rawalpindi from September, 2023 to April, 2024.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: This study included patients who were undergoing hemodialysis via a tunneled double lumen catheter with blood flow rate (BFR) of > 250 mL/min at the start of the study and without previous history of CRBSI. Exclusion Criteria: Patients with catheter dysfunction defined by a (BFR) of < 250 mL/min, allergic to used drugs, with previous history of catheter dysfunction and CRBSI, IV drug abusers, changing dialysis from catheter to AVF were excluded from the study.

Intervention groups

After every hemodialysis session, an injection TaurolockHEP500® was administered into the tunnelled double-lumen catheter in half dose for Group A (Intervention Group 1) and one-third dose for Group B (Intervention Group 2). The rest of the space in the catheter's lumen was filled with heparin. All the patients were then followed for three months.

Main outcome variables

Fever and rigors during hemodialysis CRP Blood flow rate during hemodialysis Blood culture and sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240921063106N1**
Registration date: **2024-10-01, 1403/07/10**
Registration timing: **retrospective**

Last update: **2024-10-01, 1403/07/10**
Update count: **0**

Registration date

2024-10-01, 1403/07/10

Registrant information

Name
Ghulam Mustafa
Name of organization / entity
Armed Forces Institute of Urology Rawalpindi pakistan
Country
Pakistan
Phone
+92 312 5803252
Email address
ghulammustafa842@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-15, 1402/06/24

Expected recruitment end date

2023-12-15, 1402/09/24

Actual recruitment start date

2023-09-15, 1402/06/24

Actual recruitment end date

2024-01-30, 1402/11/10

Trial completion date

2024-04-30, 1403/02/11

Scientific title
Efficacy of Half Dose and One Third Dose of Injection Taurolock® for Tunneled Double Lumen Catheter Lock Solution

Public title
Dialysis catheter lock solution
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who were undergoing hemodialysis via a tunneled double lumen catheter with blood flow rate (BFR) of > 250 mL/min at the start of the study No previous history of catheter related blood stream infection
Exclusion criteria:
Patients allergic to used drugs(TaurolockHEP500®) IV drug abusers Changing dialysis from catheter to AVF
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **314**
Actual sample size reached: **314**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using computer-generated sequences, prepared online.
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/Institutional Review board(IRB) AFIU RAWALPINDI
Street address
CMH road Rawalpindi Punjab
City
Rawalpindi
Postal code
46000
Approval date
2023-09-14, 1402/06/23
Ethics committee reference number
Uro-Adm-Trg-1/IRB/2023/006

Health conditions studied

1

Description of health condition studied
End Stage Kidney Disease patient undergoing Hemodialysis
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Blood flow rate
Timepoint
Blood flow rate during each session of hemodialysis
Method of measurement
Blood flow rate checked during hemodialysis from blood pump of dialysis machine.

2

Description
Blood culture for identifying infection
Timepoint
The blood sample will be collected if patients develops fever or shivering during or within 4 hours after hemodialysis session.
Method of measurement
The blood will be drawn from venous circulation by using strile blood sample collecting syringes. The collected sample will be transferred to and preserved in blood sample bottles.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: This group will receive a half dose of injection taurolockHEP500® into the lumens of the tunnelled catheter after each dialysis session for three months.
Category
Treatment - Drugs

2

Description

Intervention group 2:This group will receive a one-third dose of injection taurolockHEP500® into the lumens of the tunnelled catheter after each dialysis session for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Armed Forces Institute Of Urology Rawalpindi

Full name of responsible person
Ghulam Mustafa

Street address
CMH road Rawalpindi Punjab

City
Rawalpindi

Postal code
46000

Phone
+92 340 8913290

Email
ghulammustafa842@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Armed Forces Institute Of Urology Rawalpindi

Full name of responsible person
Ghulam Mustafa

Street address
CMH road Rawalpindi Punjab

City
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Postal code
46000

Phone
+92 340 8913290

Email
ghulammustafa842@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Armed Forces Institute Of Urology Rawalpindi

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
Armed Forces Institute Of Urology Rawalpindi

Full name of responsible person
Ghulam Mustafa

Position
Registrar

Latest degree
Medical doctor

Other areas of specialty/work
Nephrology

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CMH road Rawalpindi Punjab

City
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Province
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Phone
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Email
ghulammustafa842@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Armed Forces Institute Of Urology Rawalpindi

Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
Armed Forces Institute Of Urology Rawalpindi

Full name of responsible person

Ghulam Mustafa
Position
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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
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
Not applicable