

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 sterile 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

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CMH road Rawalpindi Punjab

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Phone

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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

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Email

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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

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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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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