

# 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 tunneled 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**

Rawalpindi

**Postal code**

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**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

**Street address**

CMH road Rawalpindi Punjab

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 340 8913290

**Email**

ghulammustafa842@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Armed Forces Institute Of Urology Rawalpindi

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Ghulam Mustafa

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**Contact**

**Name of organization / entity**

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**Position**

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**Latest degree**

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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