

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of different dialysate temperatures on adequacy of haemodialysis in patients with end stage renal disease

Protocol summary

Study aim

To determine the effect of dialysate temperature on adequacy of hemodialysis

Design

A two arm, parallel group, randomized trial to be carried out on minimum 50 patients at a single center.

Randomization will be computerized with concealment using opaque envelopes.

Settings and conduct

This trial would be conducted at Dialysis Unit of Pak Emirates Military Hospital. Patients would be selected by non-probability convenience sampling. Randomization would be through computer generated sequences and would be concealed in opaque envelopes. Patients would undergo haemodialysis with dialysate temperature at 37.0 or 36.0 degree Celsius. They would be blinded to the treatment strategy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients on maintenance haemodialysis for at least 3 months; Use of arteriovenous fistula

Exclusion criteria: Acute kidney injury; History of intradialytic hypotension during last one month; Shortening of haemodialysis session for any reason; Interruption in haemodialysis session for more than 5 minutes; Patients known to have central venous stenosis; Uncooperative patients; Lack of consent

Intervention groups

Intervention group 1: Dialysate Temperature 37.0 degree Celsius. Patients in this group would have the dialysate temperature set at 37.0 degree Celsius when the machine is being setup for a dialysis session and maintained throughout the 4 hours session. Intervention group 2: Dialysate Temperature 36.0 degree Celsius. Patients in this group would have the dialysate temperature set at 36.0 degree Celsius when the machine is being setup for a dialysis session and maintained throughout the 4 hours session. Ultrafiltration would be done to the usual dry weight. All sessions would be carried out on Fresenius F4008 haemodialysis

machines.

Main outcome variables

Urea reduction ratios; online Kt/V (as measured by Online Clearance Monitoring)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240511061739N1**

Registration date: **2024-06-05, 1403/03/16**

Registration timing: **registered_while_recruiting**

Last update: **2024-06-05, 1403/03/16**

Update count: **0**

Registration date

2024-06-05, 1403/03/16

Registrant information

Name

Altaf Hussain Afridi

Name of organization / entity

Pak emirate hospital

Country

Pakistan

Phone

+92 302 5757487

Email address

altafussainafri8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-30, 1403/03/10

Expected recruitment end date

2024-07-02, 1403/04/12

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of different dialysate temperatures on adequacy of haemodialysis in patients with end stage renal disease

Public title
Effect of dialysis fluid temperature in haemodialysis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients on maintenance haemodialysis for at least 3 months Use of arteriovenous fistula for haemodialysis
Exclusion criteria:
Acute kidney injury History of intradialytic hypotension during last one month Shortening of haemodialysis session for any reason Interruption in haemodialysis session for more than 5 minutes Patients known to have central venous stenosis Uncooperative patients Lack of consent

Age
From **19 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization would be done using computer generating sequencing. This would be done using online tools (calculator.net website). This would then be concealed in opaque envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients and their caregivers would be blinded to the dialysate temperature, since this is set by the dialysis technicians and the patients are not aware of these settings. This parameter would not be visible on the display panel of the machines during the haemodialysis sessions, and would thus remain concealed from the patients It would not be possible to blind the paramedical staff carrying out the dialysis sessions. However, they would have no role in data collection or analysis. Similarly, the principal investigator and two other doctors involved in data collection would not be blinded to the treatment groups. Since the outcome measures for this study are objective laboratory parameters, this lack of blinding is not expected to have a significant impact on

the results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Pak Emirates Military Hospital
Street address
The Mall Road
City
Rawalpindi
Postal code
46000

Approval date
2024-01-24, 1402/11/04

Ethics committee reference number
A/28/EC/1/24

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
Urea reduction ratio

Timepoint
At the start and end of haemodialysis session

Method of measurement
Laboratory testing for serum urea levels

2

Description
Online Kt/V

Timepoint
During the four hours haemodialysis session

Method of measurement
Online Clearance Monitoring module of Fresenius F4008 machines

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Dialysate Temperature 37.0 degree Celsius. Patients in this group would have the dialysate temperature set at 37.0 degree Celsius when the machine is being setup for a dialysis session. The same temperature of dialysate would be maintained throughout the session of 4 hours duration. Ultrafiltration would be done to the usual dry weight.

Category

Treatment - Other

2

Description

Intervention group 2: Dialysate Temperature 36.0 degree Celsius. Patients in this group would have the dialysate temperature set at 36.0 degree Celsius when the machine is being setup for a dialysis session. The same temperature of dialysate would be maintained throughout the session of 4 hours duration. Ultrafiltration would be done to the usual dry weight.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Street address

The Mall Road

City

Rawalpindi

Postal code

46000

Phone

+92 302 5757487

Email

altafhussainafridi8@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Street address

The Mall Road

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Email

altafhussainafridi8@gmail.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

Altaf Hussain

Position

Postgraduate Resident

Latest degree

Bachelor

Other areas of specialty/work

Resident Internal medicine

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Position

Postgraduate Resident

Latest degree

Bachelor

Other areas of specialty/work

Internal medicine

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

Pak Emirates Military Hospital

Full name of responsible person

Altaf hussain

Position

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Latest degree

Bachelor

Other areas of specialty/work

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

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document**When the data will become available and for how long****To whom data/document is available****Under which criteria data/document could be used****From where data/document is obtainable****What processes are involved for a request to access data/document****Comments**