Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Altafhussain Afridi
Name of organization / entity
Pak emirate hospital
Country
Pakistan
Phone
+92 302 5757487
Email address
altafhussainafridi8@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
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Phone
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Email
altafhussainafridi8@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Altaf Hussain
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46000
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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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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
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Person responsible for updating data

Contact
Name of organization / entity
Pak Emirates Military Hospial
Full name of responsible person
Altaf hussain
Position
Postgraduate Resident
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