Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Cooler Dialysate Temperature on Haemodynamic Stability in Hypotensive Patients on Maintenance Haemodialysis

Protocol summary

Study aim

The aim of this study is to investigate the effect of using a cooler dialysate temperature (35.5°C) on hemodynamic stability in hypotensive patients with end-stage renal disease (ESRD) undergoing maintenance hemodialysis, compared to the standard dialysate temperature (37°C). Hemodialysis is a critical life-saving procedure, but complications such as intradialytic hypotension can lead to session interruptions and increased morbidity and mortality. This study is the first, to our knowledge, to specifically examine the benefits of cooler dialysate in a hypotensive ESRD population, with the goal of improving hemodynamic stability during dialysis sessions.

Design

Parallel group, double blind, randomised controlled trial

Settings and conduct

Conducted in a tertiary care hospital, the study ensures blinding of participants, healthcare providers, data collectors, and outcome assessors through concealed temperature settings. The design aims to minimize bias and assess the impact of cooler dialysate on intradialytic hypotension

Participants/Inclusion and exclusion criteria

Patients from both genders between 18 and 60 years old who were on twice weekly HD and had hypotension were included. Patients with thyroid disease, anaemia, and taking anti-hypertensive medications were excluded.

Intervention groups

Cooler dialysate temperature (35.5°C) on hemodynamic stability in hypotensive patients with end-stage renal disease (ESRD) undergoing maintenance hemodialysis, compared to the standard dialysate temperature (37°C).

Main outcome variables

This double-blind, randomized trial assesses the impact of cooler dialysate (35.5°C) versus standard dialysate (37°C) on hemodynamic stability in hypotensive ESRD patients during hemodialysis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241030063550N1**
Registration date: **2025-02-07, 1403/11/19**
Registration timing: **retrospective**

Last update: **2025-02-07, 1403/11/19**
Update count: **0**

Registration date

2025-02-07, 1403/11/19

Registrant information

Name
Muhammad Haseeb Lodhi
Name of organization / entity
National University of Medical Sciences, Pakistan
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Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-01, 1403/06/11

Expected recruitment end date

2025-01-31, 1403/11/12

Actual recruitment start date

2024-09-01, 1403/06/11

Actual recruitment end date

2025-01-31, 1403/11/12

Trial completion date

2025-01-31, 1403/11/12

Scientific title
Effect of Cooler Dialysate Temperature on Haemodynamic Stability in Hypotensive Patients on Maintenance Haemodialysis

Public title
Effect of Cooler Dialysate Temperature on Haemodynamic Stability in Hypotensive Patients on Maintenance Haemodialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients from both genders. Ages between 18 to 60 years. On twice weekly Hemodialysis. Having systolic blood pressure (SBP) below 90mmHg or diastolic blood pressure (DBP) below 60mmHg or both. Patients with SBP above 90mmHg or mean arterial pressure ≥ 65 on pharmacological support .

Exclusion criteria:
Patients having thyroid disease, anaemia, taking anti-hypertensive medications, recent heart attack, not willing to participate and pregnant females.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation in this study is achieved using a computer-generated randomization sequence, prepared by an independent statistician who is not involved in the trial's conduct. Participants are assigned to either the cooler dialysate (35.5°C) or standard dialysate (37°C) group in a 1:1 ratio, with allocation concealed using sealed, opaque envelopes. These envelopes are opened only after participant enrollment by an independent technician, who then programs the dialysis machines accordingly, ensuring that neither participants nor healthcare providers can influence or predict group assignment. This method ensures a robust and unbiased randomization process.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind randomized controlled trial investigating the effect of cooler dialysate temperature on hemodynamic stability in hypotensive patients undergoing maintenance hemodialysis. Both participants and healthcare providers, including physicians and nurses, are blinded to the dialysate temperature settings. The dialysis machines are pre-programmed by an independent technician, and the temperature display is concealed to prevent unblinding. Data collectors and outcome assessors are also blinded to group allocations, analyzing anonymized data without knowledge of the intervention. The principal investigator remains blinded during data collection and analysis to minimize bias. Additionally, the Data Safety and Monitoring Board (DSMB) reviews coded, anonymized data to ensure safety and efficacy without compromising blinding. This double-blind design ensures the integrity and reliability of the study outcomes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Pakistan Emirates Military Hospital

Street address
Rawalpindi

City
Rawalpindi

Postal code
46000

Approval date
2024-08-01, 1403/05/11

Ethics committee reference number
ERC/178/24

Health conditions studied

1

Description of health condition studied
Hypotension in Hemodialysis patients

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Intradialytic hypotension comparison in patients of CKD on maintenance hemodialysis

Timepoint
During the HD session, intradialytic blood pressure and

pulse rate changes were documented every hour and at the end of the session.

Method of measurement

BP measured with Sphygmomonometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: standard 4hrs hemodialysis with fresenius 4008 series hemodialysis machines, with standard flow rate of 450 to 500ml per min, with cooler dialysate temperature (35.5°C)

Category

Treatment - Other

2

Description

Control group: standard 4hrs hemodialysis with fresenius 4008 series hemodialysis machines, with standard flow rate of 450 to 500ml per min, with standard dialysate temperature (37°C)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Pakistan Emirates Military Hospital Dialysis Centre

Full name of responsible person
Muhammad Haseeb Lodhi

Street address
Rawalpindi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National University Of Medical Sciences

Full name of responsible person
Dr Abdul Rehman

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Rawalpindi

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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
National University Of Medical Sciences

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
National University Of Medical Sciences

Full name of responsible person
Muhammad Haseeb Lodhi

Position
Registrar Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Muhammad Haseeb Lodhi

Position

Registrar Medicine

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Effect of Cooler Dialysate Temperature on Haemodynamic Stability in Hypotensive Patients on Maintenance Haemodialysis

When the data will become available and for how long

Mar 25

To whom data/document is available

Anyone who requests via email after sharing purpose of requirement

Under which criteria data/document could be used

After taking consent from authors

From where data/document is obtainable

Via email request

What processes are involved for a request to access data/document

Email request

Comments