

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

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 $\geq$ 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 Sphygmomanometer

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

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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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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

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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