

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of different dialysate sodium concentrations on blood pressure response during hemodialysis

Protocol summary

Study aim

To determine the dialysate sodium concentration that results in normotensive response during hemodialysis

Design

Pragmatic, community based, parallel group, single blind, randomized controlled trial. Sample size would be 105.

Settings and conduct

Study would be conducted in Hemodialysis Centre of Pak Emirates Military Hospital, Rawalpindi , Punjab, Pakistan. Patients have been blinded and they would not know that to which group of dialysate sodium concentration they belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 18 years or more 2. Either Genders 3. CKD patients undergoing routine hemodialysis for 3 months or more 4. Hemodynamically stable patients Exclusion criteria: 1. Age less than 18 years 2. Patients undergoing routine hemodialysis for less than 3 months 3. Patients undergoing hemodialysis for causes other than CKD 4. Hemodynamically Unstable patients 5. Ongoing Sepsis, Active Cancer, MI" 6. Patient's unwillingness

Intervention groups

Group 1: Dialysate Sodium Concentration of 135 mEq
Group 2: Dialysate Sodium Concentration of 140 mEq
Group 3: Dialysate Sodium Concentration of 145 mEq

Main outcome variables

Hypertension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240321061342N1**

Registration date: **2025-02-20, 1403/12/02**

Registration timing: **retrospective**

Last update: **2025-02-20, 1403/12/02**

Update count: **0**

Registration date

2025-02-20, 1403/12/02

Registrant information

Name

Muhammad Abdul Haseeb Siddiqui

Name of organization / entity

National University of Medical Sciences

Country

Pakistan

Phone

+92 51 5157412

Email address

haseeb9876@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-01, 1403/07/10

Expected recruitment end date

2024-10-15, 1403/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of different dialysate sodium concentrations on blood pressure response during hemodialysis

Public title

Effect of different dialysate sodium concentrations on blood pressure response during hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 or greater Either Genders CKD patient on regular hemodialysis for 3 months or more Hemodynamically stable patient
Exclusion criteria:
Age less than 18 years Patient undergoing dialysis for reasons other than CKD CKD patient undergoing routine hemodialysis for less than 3 months Hemodynamically Unstable patient Ongoing sepsis, active cancer Patient unwillingness
Age
From 18 years old
Gender
Both
Phase
N/A
Groups that have been masked
Participant
Sample size
Target sample size: 100
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be done. Each participant is randomly assigned to a treatment group using a random number generator.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants in the study would not know that to which group of dialysate sodium concentration during hemodialysis they have been allotted to.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

<u>1</u>
Ethics committee
Name of ethics committee
Pak Emirates Military Hospital Ethical Committee
Street address
Pak Emirates Military Hospital, Abid Majeed Road, Saddar , Rawalpindi Cantt.
City
Rawalpindi
Postal code
45000
Approval date
2024-02-10, 1402/11/21
Ethics committee reference number
A/28/ERC/27/24

Health conditions studied

<u>1</u>
Description of health condition studied
Chronic Kidney Disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

<u>1</u>
Description
Blood pressure Response during hemodialysis with different dialysate sodium concentrations
Timepoint
Blood pressure before, 2 hours midway dialysis and after completion of hemodialysis.
Method of measurement
Measure blood pressure with sphygmomonometer

Secondary outcomes

<u>1</u>
Description
Timepoint
Method of measurement

Intervention groups

<u>1</u>
Description
Intervention group 1: Dialysate Sodium Concentration of 135 mEQ during hemodialysis
Category
Treatment - Other

<u>2</u>
Description
Intervention group 2: Dialysate Sodium Concentration of 140 mEQ during hemodialysis
Category
Treatment - Other

<u>3</u>
Description
Intervention group 3: Dialysate Sodium Concentration of 145 mEQ during hemodialysis
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis Centre of Pak Emirates Military Hospital
Rawalpindi

Full name of responsible person

Dr Muhammad Abdul Haseeb Siddiqui

Street address

Pak Emirates Military Hospital, Abid Majeed Road,
Saddar

City

Rawalpindi

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Phone

+92 313 5411980

Email

haseeb9876@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National University of Medical Sciences

Full name of responsible person

Muhammad Abdul Haseeb Siddiqui

Street address

NUMS, The Mall Road, Saddar , Rawalpindi

City

Rawalpindi

Postal code

46000

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+92 313 5411980

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haseeb9876@gmail.com

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

Pak Emirates Military Hospital

Full name of responsible person

Dr Muhammad Abdul Haseeb Siddiqui

Position

Registrar Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Dr Abdul Rehman Arshad

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

Street address

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haseeb9876@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Dr Muhammad Abdul Haseeb Siddiqui

Position

Registrar Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Abid Majeed Road, Saddar , Rawalpindi

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Postal code

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It will be available on contacting via provided email ID.

When the data will become available and for how long

After publication of research article.

To whom data/document is available

It will be available on contacting via provided email ID.

Under which criteria data/document could be used

Will be provided to medical professionals upon contacting and stating their need for data.

From where data/document is obtainable

It will be available on contacting via provided email ID.

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

It will be available on contacting via provided email ID.

Comments

It will be available on contacting via provided email ID.