# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Universiry 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 rountine 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

### 1

**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

### 1

**Description of health condition studied**
Chronic Kidney Disease

**ICD-10 code**
N18.5

**ICD-10 code description**
Chronic kidney disease, stage 5

## Primary outcomes

### 1

**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

### 1

**Description**

**Timepoint**

**Method of measurement**

## Intervention groups

### 1

**Description**
Intervention group 1: Dialysate Sodium Concentration of 135 mEQ during hemodialysis

**Category**
Treatment - Other

### 2

**Description**
Intervention group 2: Dialysate Sodium Concentration of 140 mEQ during hemodialysis

**Category**
Treatment - Other

### 3

**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

**Postal code**
45000

**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

**Phone**
+92 313 5411980

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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**
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

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Pak Emirates Military Hospital, Rawalpindi

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
Dr Abdul Rehman Arshad

**Position**
Associate Professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Nephrology

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Abid Majeed Road, Saddar

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## Person responsible for updating data

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**Latest degree**
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**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**
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.