

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of low and normal levels of sodium in the dialysis fluid on the levels of calcium, phosphorus and parathyroid hormone in patients undergoing chronic hemodialysis

#### Protocol summary

##### Study aim

Determining the effect of sodium in the dialysis fluid on the level of calcium, phosphorus and parathyroid hormone in chronic hemodialysis patients

##### Design

A double-blind randomized controlled clinical trial will be conducted on 80 patients undergoing chronic hemodialysis.

##### Settings and conduct

In this randomized controlled clinical trial study, 80 chronic hemodialysis patients referring to the dialysis center of Ahvaz Golestan Hospital will be included after considering the inclusion and exclusion criteria. The number of each patient will be placed on the medication envelope based on the randomization list of the software. The sodium solutions will be packaged in such a way that the patient will not know the amount of sodium in the dialysis solution and will be performed by a nurse unrelated to the research so that the project manager will not know about it. Then, a group of 40 people will be treated with hemodialysis with liquid sodium 140 and another group will be treated with liquid sodium 135 milliequivalent/liter. Before the start of hemodialysis, then 1 month and 3 months after the start of dialysis, serum calcium, phosphorus and hormones. The patient's parathyroid will be checked and compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: chronic hemodialysis patients aged 18 to 60 years Exclusion criteria: the presence of any uncontrolled background disease, presence of active infection, drop in systolic or diastolic blood pressure more than 20 mmHg compared to the patient's baseline pressure, the occurrence of frequent muscle cramps that cannot be found in the investigation of the cause other than low sodium. The patient's sodium is less than 130 mEq/L.

##### Intervention groups

Patients will be randomly divided into two groups receiving sodium 135 and 140 mEq/L

##### Main outcome variables

Calcium, phosphorus and parathyroid hormone levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231217060445N1**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **prospective**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

##### Registration date

2023-12-30, 1402/10/09

##### Registrant information

##### Name

Ladan Mirzaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3320 4501

##### Email address

dr.l.mirzaei@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-21, 1402/11/01

##### Expected recruitment end date

2024-10-22, 1403/08/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of low and normal levels of sodium in the dialysis fluid on the levels of calcium, phosphorus and parathyroid hormone in patients undergoing chronic hemodialysis

**Public title**  
Determining the effect of sodium levels of dialysis fluid on the levels of calcium, phosphorus and parathyroid hormone in patients undergoing chronic hemodialysis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Chronic hemodialysis patients aged 18 to 60 years  
**Exclusion criteria:**  
The presence of any uncontrolled underlying disease (such as pheochromocytoma or other cardio-pulmonary and liver diseases) Presence of active infection Occurrence of frequent muscle cramps that cannot be found due to low sodium. Patient's sodium is less than 130 mEq/L Systolic or diastolic blood pressure drop of more than 20 mm Hg compared to the patient's baseline pressure.

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Using a calculator, random numbers from 1 to 80 were generated. 40 numbers and the first number produced by the calculator were assigned to the intervention group and the next 40 numbers to the control group, then the packet of soluble sodium was given to the researcher in order from 1 to 40 to prescribe to the nurse.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Sodium solution will be in similar packages. The number of each patient will be placed on the medication envelope based on the randomization list of the software. Only the nurse will be aware of the number assigned to the relevant group. Then, from 1 to 80, the sodium solution will be available to the nurse to administer to the patients. The patient will not know the amount of sodium used in the dialysis solution and it will

be done by a nurse not related to the research, so the performing doctor will not know about it.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

##### Street address

Golestan town, Golestan Blvd, Jundishapur University of Medical Sciences

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

#### Approval date

2023-12-02, 1402/09/11

#### Ethics committee reference number

IR.AJUMS.REC.1402.470

## Health conditions studied

### 1

#### Description of health condition studied

Patients undergoing chronic hemodialysis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

calcium

#### Timepoint

Before starting the study, one and three months after dialysis

#### Method of measurement

blood test

### 2

#### Description

phosphorus

#### Timepoint

Before starting the study, one and three months after dialysis

## Method of measurement

Blood test

### 3

#### Description

Parathyroid hormone

#### Timepoint

Before starting the study, one and three months after dialysis

#### Method of measurement

Blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: the group that will undergo hemodialysis with a sodium solution of 135 mEq/L.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: the group that will undergo hemodialysis with sodium solution of 140 mEq/L.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahvaz Golestan Hospital

##### Full name of responsible person

Ladan Mirzaei

##### Street address

Golestan Ave, Golestan Hospital, Ahvaz

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8328

##### Email

dr.l.mirzaei@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehrnoush Zakerkish

##### Street address

Golestan Town, Golestan Blvd., Research and Technology Development Vice-Chancellor.  
Jundishapur University of Medical Sciences

##### City

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##### Province

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##### Phone

+98 61 3337 8628

##### Email

info@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Ladan Mirzaei

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

Golestan Ave., Golestan Hospital

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##### Province

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**Email**  
dr.l.mirzaei@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences

**Full name of responsible person**  
Asieh Aref

**Position**  
Associate professor

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
Nephrology

**Street address**  
Golestan Ave., Golestan Hospital

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**Email**  
aref-a@ajums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences

**Full name of responsible person**  
Ladan Mirzaei

**Position**  
resident

**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
Internal Medicine

**Street address**

Golestan St., Golestan Hospital

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**Province**  
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**Postal code**  
6135715794

**Phone**  
+98 61 3373 8628

**Email**  
dr.l.mirzaei@gmail.com

## 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

Yes - There is 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

Information about the main outcome or similar can be shared.

### When the data will become available and for how long

The access period starts 6 months after the results are published

### To whom data/document is available

No

### Under which criteria data/document could be used

No

### From where data/document is obtainable

Dr. Ladan Mirzaei

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

Communicate with the responsible person

### Comments