

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The effect of low sodium level in dialysis fluid on patients hemodynamic undegoing chronic hemodialysis

#### Protocol summary

##### Study aim

Determining the effect of low sodium level of dialysis fluid on hemodynamics of chronic hemodialysis patients

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 80 patients. Data analysis will be done with spss software.

##### Settings and conduct

It was done in a double-blind manner. The patients are divided into two groups of 40 people, they undergo hemodialysis with 135 and 140 sodium dialysis liquid, and after three months, the effect of dialysis liquid sodium on hemodynamics and the complications caused by it are investigated in the two groups. Golestan and Imam (RA) Ahvaz Hospital Dialysis Center

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: adults undergoing chronic hemodialysis  
Inclusion criteria: active infection, ascites, uncontrolled blood pressure, age less than 18 and more than 60 years, complications during dialysis if not due to sodium reduction in dialysis fluid.

##### Intervention groups

Reducing sodium in dialysis fluid (135) in order to reduce blood pressure and weight of chronic hemodialysis patients in the intervention group and no change in sodium in dialysis fluid (140) in the control group

##### Main outcome variables

Hypotension, muscle cramps

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230704058662N1**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **prospective**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

##### Registration date

2023-08-09, 1402/05/18

##### Registrant information

###### Name

Azin Amoozadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 918 990 9989

###### Email address

azinamoozadeh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of low sodium level in dialysis fluid on patients hemodynamic undegoing chronic hemodialysis

##### Public title

The effect of low sodium level in dialysis fluid on patients hemodynamic undegoing chronic hemodialysis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Adults on chronic hemodialysis

**Exclusion criteria:**

Age less than 18 Age more than 60 Uncontrolled underlying disease Presence of active infection Ascites Sodium less than 130 Hypotension Muscle cramps

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patient and the therapist are uninformed, and among the patients undergoing chronic hemodialysis in the mentioned dialysis centers, they are randomly divided into two groups with sodium 135 and sodium 140 dialysis fluid based on the bed number (even or odd) And the nurse in charge of the dialysis department only knows about dialysis fluid sodium, and all patient information is recorded by another nurse who does not know about dialysis fluid sodium.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participant, the researcher, and the treatment staff are kept blind, and dialysis liquid sodium is adjusted by a nurse not related to the research

**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 Hospital, Farvardin Street

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6441945781

**Approval date**

2023-05-27, 1402/03/06

**Ethics committee reference number**

IR.AJUMS.REC.1402.122

**Health conditions studied**

**1**

**Description of health condition studied**

Chronic hemodialysis

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Decrease of blood pressure

**Timepoint**

The beginning of the study and months 1, 2 and 3

**Method of measurement**

Mercury sphygmomanometer

**2**

**Description**

Reduction of patient antihypertensive drugs

**Timepoint**

The beginning of the study and months 1, 2 and 3

**Method of measurement**

Mercury sphygmomanometer and history

**3**

**Description**

Decrease of weight

**Timepoint**

The beginning of the study and months 1, 2 and 3

**Method of measurement**

Scales

**4**

**Description**

Muscle cramps

**Timepoint**

The beginning of the study and months 1, 2 and 3

**Method of measurement**

History and physical examination

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Dialysis liquid sodium 135, hemodialysis three to four times a week for three months

### Category

Treatment - Other

## 2

### Description

Control group: dialysis liquid sodium 140, hemodialysis three to four times a week for three months

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golestan Ahvaz Hospital Hemodialysis Center

##### Full name of responsible person

Asieh Aref

##### Street address

Farvardin Street

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6441945781

##### Phone

+98 61 3573 3118

##### Fax

+98 61 3337 4058

##### Email

info@ajums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Hemodialysis Center of Imam khomeini Ahvaz Hospital

##### Full name of responsible person

Fatemeh Hayati

##### Street address

24 meter street

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6193673166

##### Phone

+98 61 3292 3985

##### Email

info@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Asieh Aref

##### Street address

Golestan Boulevard, West sahel Boulevard

##### City

ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

##### Phone

+98 61 3311 0000

##### 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

Azin Amoozadeh

##### Position

Internal resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

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Golestan Hospital, Farvardin St , West sahel Blvd

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

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**Position**

Academic board

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Asieh Aref

**Position**

Academic board

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Golestan Hospital, Farvardin Street, West saheli Boulevard

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**Province**

Khuzestan

**Postal code**

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**Phone**

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**Email**

aref-a@ajums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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