

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Evaluation of the cardiac function in chronic hemodialysis patients with low sodium levels in the dialysis fluid

#### Protocol summary

##### Study aim

Examination of cardiac function in chronic hemodialysis patients with low sodium levels in the dialysis fluid

##### Design

A controlled, parallel-group, double-blind, randomized clinical trial on 80 patients.

##### Settings and conduct

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

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: adults under chronic hemodialysis.

Exclusion criteria: active infection, ascites, uncontrolled blood pressure, age less than 18 and more than 60 years, complications during dialysis if not due to sodium depletion of the dialysis fluid.

##### Intervention groups

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

##### Main outcome variables

Blood pressure; Muscle cramps

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230824059250N1**

Registration date: **2023-08-30, 1402/06/08**

Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**

Update count: **0**

##### Registration date

2023-08-30, 1402/06/08

##### Registrant information

###### Name

Masud Rahmani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 114 8109

###### Email address

rahmani.ma@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-12-22, 1402/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the cardiac function in chronic hemodialysis patients with low sodium levels in the dialysis fluid

##### Public title

The effect of low sodium level of dialysis fluid on cardiac function of chronic hemodialysis patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Adults undergoing chronic hemodialysis

**Exclusion criteria:**

Age less than 18, age more than 60 Uncontrolled underlying disease Presence of active infection Sodium acetate less than 130 Low blood pressure Muscle cramps

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients with eligibility criteria will be divided into two groups using a randomized block design. An online website (<https://www.sealedenvelope.com>) generates a random list based on the desired sample size and block size of 4. After creating a list, each patient will be identified with a unique code throughout the study. 40 people are selected for the first intervention group and 40 for the second intervention group. While the patients and the therapist do not know the amount of sodium received.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

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

**Placebo**

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**

Farvardin Street, Golestan Hospital

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6441945781

**Approval date**

2023-05-27, 1402/03/06

**Ethics committee reference number**

IR.AJUMS.REC.1402.123

**Health conditions studied****1****Description of health condition studied**

Chronic hemodialysis

**ICD-10 code**

I95.3

**ICD-10 code description**

Hypotension of hemodialysis

**Primary outcomes****1****Description**

Blood pressure

**Timepoint**

The beginning of the study (before the start of the intervention) and 1, 2 and 3 months after the intervention

**Method of measurement**

Mercury sphygmomanometer

**2****Description**

Muscle cramps

**Timepoint**

The beginning of the study (before the start of the intervention) and 1, 2 and 3 months after the intervention

**Method of measurement**

History and physical examination

**3****Description**

Efficacy of blood pressure lowering drugs used by the patient

**Timepoint**

The beginning of the study (before the start of the intervention) and 1, 2 and 3 months after the intervention

**Method of measurement**

Sphygmomanometer and history

**Secondary outcomes****1****Description**

Weight

**Timepoint**

The beginning of the study (before the start of the intervention) and 1, 2 and 3 months after the

intervention  
**Method of measurement**  
scale

+98 912 114 8109  
**Email**  
rahmani.ma@ajums.ac.ir

## 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**

Intervention group: Sodium dialysis fluid, 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**

Ekhlas Torfi

##### **Street address**

Farvardin St

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6441945781

##### **Phone**

+98 61 3314 0000

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##### **Email**

torfi-e@ajums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Hemodialysis Center, Imam Khomeini Hospital, Ahvaz

##### **Full name of responsible person**

Masud Rahmani

##### **Street address**

24 meter street

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6193673166

##### **Phone**

## Sponsors / Funding sources

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Mehrnoosh Zakerkish

##### **Street address**

Farvardin St

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6135715794

##### **Phone**

+98 61 3314 0000

##### **Email**

zakerkish-m@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**

Masud Rahmani

##### **Position**

Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Cardiology

##### **Street address**

Farvardin Street, Golestan Hospital

##### **City**

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## Person responsible for scientific inquiries

### Contact

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Ahvaz University of Medical Sciences  
**Full name of responsible person**  
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Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**  
Masud Rahmani  
**Position**  
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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)

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

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable