

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

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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

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2

Recruitment center

Name of recruitment center

Hemodialysis Center, Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Masud Rahmani

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24 meter street

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Postal code

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Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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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

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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