

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 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

Khouzestan

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

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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

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Internal Medicine

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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

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