Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Khouzestan

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
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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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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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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