

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of the gradual reduction of liquid sodium dialysis hypotension, muscle cramps and plasma sodium levels in hemodialysis patients

Protocol summary

Summary

The purpose of this study was to evaluate the effect of gradual reduction of sodium dialysis fluid on the occurrence of hypotension, muscle cramps and plasma sodium levels in dialysis patients. The relationship between calcium and magnesium with cramp is also assessed and randomized and triple blind clinical trials. Entry: Patients with end-stage renal failure, aged 75-18, who have been undergoing hemodialysis 2-3 times a week for at least two months, and patients who are willing to participate in the project. Exit criteria: Patients who use anti-cramp therapy, patients diagnosed by a physician Blood pressure is not controlled, use of low blood pressure medications in the morning Before dialysis, the presence of a pacemaker is a heart attack such as a heart attack during the last six months and a discharge fraction of less than 30%. The sample size is 106 people. In the first intervention, the patients in the control group were routinized (sodium dialysis solution mEq / l138 in the total duration of dialysis) and the patients in the test group gradually reduced the sodium dialysis solution (starting with 150 mEq / l and reducing it every 15 minutes and then fixing it This concentration will be dialysed for three sessions. Subsequently, both groups undergo dialysis with routine three sessions. Then, using the cross over method, the patients will be replaced in two groups and both groups will dial for three sessions. At this time, patients will be checked for 5 times the blood pressure and muscle cramps are asked and sodium / calcium / magnesium before And after dialysis, it is checked at all stages

General information

Acronym

interventional

IRCT registration information

IRCT registration number: **IRCT2017040833295N1**

Registration date: **2017-07-27, 1396/05/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name

Uosra Majidi

Name of organization / entity

Shahrood University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

State Shahrood University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the gradual reduction of liquid sodium dialysis hypotension, muscle cramps and plasma sodium levels in hemodialysis patients

Public title

The effect of the gradual change in liquid sodium dialysis hypotension and cramps and blood sodium dialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria include patients with end-stage renal failure (ESRD); patients aged between 75 and 18, who have been undergoing hemodialysis 2-3 times a week for at least two months; and patients who are willing to participate in the plan. Exclusion criteria include patients who use anti-cramp medication; patients who are not under the control of their physician's blood pressure department; use of medications to lower blood pressure in the morning before dialysis; heart disease, such as heart attack, over a period of six months Recent; patients with discharge fraction of less than 30%; the presence of pacemakers in patients.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

7th Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Postal code

Approval date

2017-05-24, 1396/03/03

Ethics committee reference number

ir.shmu.rec.1396.35

Health conditions studied

1

Description of health condition studied

kidney disease

ICD-10 code

N19

ICD-10 code description

Unspecified kidney failure

Primary outcomes

1

Description

Blood pressure

Timepoint

Before dialysis, first, second and third and fourth hours of dialysis, the dialysis

Method of measurement

-Br millimeters of mercury using mercury manometer

2

Description

Muscle cramps

Timepoint

Before dialysis, during dialysis, the dialysis

Method of measurement

questionnaire

3

Description

Plasma sodium

Timepoint

Before dialysis, the dialysis

Method of measurement

In terms of mEq per liter by laboratories

Secondary outcomes

1

Description

Hypotension during dialysis

Timepoint

Before dialysis, during dialysis, the dialysis

Method of measurement

-Br millimeters of mercury using mercury manometer

2

Description

Magnesium is the blood

Timepoint

Pre-dialysis and dialysis later

Method of measurement

Mg / dl

3

Description

Calcium of the blood

Timepoint

Pre-dialysis and dialysis later

Method of measurement

Mg / dl

Intervention groups

1

Description

Patients in the control group treated with routine method (sodium dialysis solution 138 meq per liter in total duration of dialysis) for three sessions of dialysis and then both intervention and control groups for a week routine dialysis were (Wash Out) using cross over of patients in the two groups will change and both groups for one week (three days) dialysis will be in both patients twice a week dialysis during the three sessions of dialysis evaluated fall.

Category

Prevention

2

Description

Intervention group patients on hemodialysis with the gradual reduction of sodium dialysis solution (starting with 150 meq per liter and cut it every 15 minutes, and then maintain this concentration) for one week (three days) will be dialysis. Both intervention and control groups for a week routine dialysis were (Wash Out) then using a cross over of patients in both groups will change and both groups for one week (three days) Dialysis and will both groups of patients who are on dialysis twice a week during the three sessions of dialysis evaluated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrood Hospital and research of Imam Hussein (AS)

Full name of responsible person

Doctor Hossein Ebrahimi

Street address

Imam Hossein Hospital, Imam Hossein Square,
Shahrood

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Doctor Hossein Ebrahimi

Street address

Hafte-Tir Square

City

Shahrood

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahrood University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Uosra Majidi

Position

Graduate student care

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

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Ali Abbasi

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Other areas of specialty/work

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Sharing plan

Person responsible for updating data

Contact
Name of organization / entity
Shahrood University of Medical Sciences
Full name of responsible person
Uosra Majidi
Position
Graduate student Care
Other areas of specialty/work
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Kosar hospital
City
Semnan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty