

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of dialysates with 2meq/l and 3meq/l potassium as a result of adding KCl on serum potassium levels of patients before and after hemodialysis in hemodialysis patients

Protocol summary

Study aim

Comparison of the effect of dialysates with 2meq/l potassium and 2meq/l potassium as a result of adding KCl on serum potassium levels of patients before and after hemodialysis in hemodialysis patients

Design

A clinical trial with a control group, based on the community, with parallel groups, with the blinding of the data analyst, randomized phase3, on 160patients. For randomization, block randomization of four of the sites sealedenvelope.com

Settings and conduct

First, the serum potassium of the patients will be measured. Then, the case group will undergo dialysis with 2meq/l potassium dialysate, to which 17.5 cc ampoules of potassium chloride 15% added to each liter. The control group will undergo dialysis with 2meq/l potassium dialysate. After the end of dialysis, the serum potassium of the patients will be measured once again immediately and once 6hours after the end of dialysis. In this blinding study the person in charge of analyzing and analyzing the data will not be aware of the intervention received by each person. Hemodialysis Department of Khurshid Hospital, Isfahan September 2022

Participants/Inclusion and exclusion criteria

Age more than 20 years and less than 75 Have a regular treatment plan and undergo hemodialysis 3 times a week Have a serum potassium level of less than and equal to 4.5

Intervention groups

The group1 will undergo dialysis with 2meq/l potassium dialysate, to which 17.5cc ampoules of potassium chloride 15% have been added to each liter of concentrated dialysate. The group2 will undergo dialysis with 2meq/l potassium dialysate.

Main outcome variables

patients serum potassium before and after dialysis

dialysate potassium before and after dialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220703055361N1**

Registration date: **2023-02-19, 1401/11/30**

Registration timing: **retrospective**

Last update: **2023-02-19, 1401/11/30**

Update count: **0**

Registration date

2023-02-19, 1401/11/30

Registrant information

Name

Mehran Haddadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 7276

Email address

haddadi.mehran@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of dialysates with 2meq/l and 3meq/l potassium as a result of adding KCl on serum potassium levels of patients before and after hemodialysis in hemodialysis patients

Public title

Effect of Different dialysates on serum potassium

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

hemodialysis for more than 3 months stable physical and laboratory condition regular treatment program (3 times dialysis per week) stable vascular access stable blood pressure stable hemodynamic and cardiovascular condition serum potassium less than or equal to 4.5 The patient should be hospitalized. (for the convenience of measuring potassium 6 hours after the end of dialysis)

Exclusion criteria:

need a blood transfusion for any reason

AgeFrom **20 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **160****Randomization (investigator's opinion)**

Randomized

Randomization description

For this purpose, we will use the block randomization method. For this purpose, the website <https://www.sealedenvelope.com/> will be used. 40 blocks of 4 will be created by the site, which will assign 2 people to the Case group and 2 people to the Control group in each block.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Research Ethics Committees of Research Ethics Committee of the "Alzahra Research Centers"

Street address

Address: Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4 - University Research and Technology Vice-Chancellor

City

اصفهان

Province

Isfahan

Postal code

۷۳۴۶۱۸۱۷۴۶

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.ARI.MUI.REC.1401.027

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

hyperkalemia in hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

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

serum potassium level

Timepoint

Measurement of serum potassium in patients before dialysis, immediately after dialysis, 6 hours after dialysis

Method of measurement

Serum potassium measurement of patients in the laboratory by electrode method and using EasyLyte REF 2124 device

2**Description**

dialysate potassium level

Timepoint

Measurement of potassium level of dialysate during dialysis from afferent and efferent coupling

Method of measurement

dialysate potassium measurement in the laboratory by electrode method and using EasyLyte REF 2124 device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Dialysis with 2 meq/l potassium dialysate to which 17.5 cc ampoules of 15% potassium chloride have been added per liter of concentrated dialysis solution (equivalent to 3 meq/l solution)

Category

Treatment - Other

2

Description

Control group: Dialysis with 2 meq/l potassium dialysate

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

khoshid medical educational research complex

Full name of responsible person

Abdolamir Atapour

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No. 105, Ostandari Street, Isfahan, Isfahan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr gholamreza Asgari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehran Haddadi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available