Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of dialysates with 2meq/l and 3meq/l potassium as a result of adding KCl onserum 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 which17.5 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 than20 years and less than75 Have a regular treatment plan and undergo hemodialysis 3times a week Have a serum potassium level of less than and equal to4.5

Intervention groups

The group1 will undergo dialysis with2meq/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 onserum 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 labaratory 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

Age
From **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
Isfehan
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
khorshid medical educational research complex

Full name of responsible person
Abdolamir Atapour

Street address
No. 105, Ostandari Street, Isfahan, Isfahan Province

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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

Street address
building no.4, isfahan university of medical sciences, hezar jirib street, isfahan

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817467346

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research@mui.ac.ir

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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Latest degree
A Level or less

Other areas of specialty/work
Internal Medicine

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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

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