Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Studying the effect of increasing dialysis solution osmolality on dialysis adequacy among patients at the dialysis center of Golestan Hospital, Ahvaz

Protocol summary

Study aim

The aim of this study is to investigate the improvement of dialysis adequacy by increasing the osmolality of the dialysate solution.

Design

This is a two-arm clinical trial in which patients were randomly assigned to two groups, A and B, using sealed envelope software, conducted in a single-blind manner on 40 participants.

Settings and conduct

This trial will be conducted at the dialysis center of Golestan Hospital, Ahvaz. Two vials of 50% glucose will be added to the dialysate solution for one group, while the other group will receive no addition; in the next session, the two groups will be crossed over. The patients will not know in which session the glucose vial was added, but the therapist will know.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study consist of adults aged 18–70 years undergoing chronic hemodialysis, with a minimum dialysis duration of three months, and the absence of malignant diseases or thyroid disorders. The exclusion criteria are defined as serum potassium levels exceeding 5.5 mEq/L; blood glucose levels above 250 mg/dL; any uncontrolled underlying medical condition or disease; active infection.

Intervention groups

In this study, two vials of 50% glucose are added to the dialysis solution of patients in the intervention group, and dialysis adequacy is calculated; however, in the control group, dialysis adequacy is calculated without adding glucose solution.

Main outcome variables

Dialysis adequacy; Blood glucose; Serum phosphorus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260721070285N1**
Registration date: **2026-10-20, 1405/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-20, 1405/07/28**
Update count: **0**

Registration date

2026-10-20, 1405/07/28

Registrant information

Name

amin ebrahimi behbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3322 1356

Email address

nfamin200@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-10-17, 1405/07/25

Expected recruitment end date

2026-10-29, 1405/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Studying the effect of increasing dialysis solution osmolality on dialysis adequacy among patients at the dialysis center of Golestan Hospital, Ahvaz

Public title
Studying the effect of increasing dialysis solution osmolality on dialysis adequacy among patients at the dialysis center of Golestan Hospital, Ahvaz

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
History of dialysis for at least three months Absence of malignant diseases or thyroid dysfunctions

Exclusion criteria:
Patients with serum potassium levels greater than 5.5 mEq/L. Blood glucose levels above 250 mg/dL. Presence of any uncontrolled underlying medical condition or disease. Presence of an active infection.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be initially randomized into two equal groups (A and B). In the last session of the first week, group A will receive dialysis with glucose-supplemented dialysate and group B with glucose-free dialysate. In the last session of the following week, the regimens will be crossed over: group A will receive glucose-free and group B will receive glucose-supplemented dialysate.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are blinded to the session in which glucose is added, whereas the healthcare providers are not blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jundishapur University Ethics Committee

Street address
Golestan Boulevard, Ahvaz Jundishapur University of Medical Sciences, Central Organization, Deputy of Research and Technology (Ground Floor).

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2026-08-01, 1405/05/10

Ethics committee reference number
IR.AJUMS.REC.1405.206

Health conditions studied

1

Description of health condition studied
End stage renal diseaase

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Dialysis adequacy

Timepoint
Measurement of dialysis adequacy for one session without adding glucose solution and one session with glucose solution

Method of measurement
Kt/V formula

2

Description
Blood glucose

Timepoint
Before and after dialysis

Method of measurement
From a blood sample

3

Description
Serum phosphorus of the patient

Timepoint
Before and after dialysis

Method of measurement
From a blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Two vials of 50% glucose (50 cc each) are added to the dialysate solution during one dialysis session, and its effect on the patient's dialysis adequacy is evaluated.
Category
Treatment - Drugs

2

Description
Control group: Control group: Hemodialysis is performed without adding glucose vials to the dialysate solution, and dialysis adequacy is evaluated without the solution.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gholestan hospital
Full name of responsible person
amin ebrahimi bebahani
Street address
Clinical Research Development Unit, Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences
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6193673166
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crdu@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abdullah Rafiei
Street address
Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
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rafiei-a@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
Amin Ebrahimi
Position
Resident
Latest degree
Specialist
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)
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
Only the information used in the study will be made available separately.
When the data will become available and for how long
6 months after publication
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Having an ethics code
From where data/document is obtainable
An email will be sent to them.
What processes are involved for a request to access data/document
To provide the research ethics code and state the reason for needing the data.
Comments