

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of cool temperature dialysate on nausea in hemodialysis patients

Protocol summary

Study aim

Determining the effect of cold fluid hemodialysis on the rate of nausea in patients under hemodialysis

Design

60 Patients under hemodialysis are randomly divided into two groups: cool dialysate and standard dialysate. The study is single blind clinical trial.

Settings and conduct

This study will be performed on 30 patients in the intervention group and 30 patients in the control group in the dialysis section Emam reza Hospital who have inclusion criteria and will randomly be divided into two groups. In this study , patients will be blinded. For 1 weeks, the intervention group is dialyzed at 36 ° C and the control group at 37 ° C is dialyzed. Amount of nausea in both groups will be evaluated with Visual Analogue Scale(VAS) at pre, intra & post dialysis

Participants/Inclusion and exclusion criteria

Inclusion criteria: Perform hemodialysis three times a week for 3-4 hours each time History of hemodialysis for at least six months Complete patient satisfaction to participate in this study Be at least 18 years old and at most 65 years old Do not take anti-nausea and vomiting medications Exclusion criteria: . Patients whose hemodialysis changes frequently and for whatever reason (changes in hemodialysis pattern). . Patients with fever and chills Death, travel or transfer of patients to other medical centers Patients' Lack of willingness of patients to continue cooperation

Intervention groups

In the intervention group hemodialysis will be done using dialysis solution with a temperature of 36 ° C. In control group hemodialysis will be done with standard solution temperature of 37 ° C and will be assessed its effect on nausea.

Main outcome variables

Nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200530047597N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

yasem arghide

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3334 8119

Email address

arghideyasem@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cool temperature dialysate on nausea in hemodialysis patients	
Public title	The effect of hemodialysis with cold fluid on nausea
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: Perform hemodialysis three times a week for 3-4 hours each time History of hemodialysis for at least six months Full patient satisfaction to participate in this study Age older than 18 years and maximum 65 years Do not take anti-nausea and vomiting medications Exclusion criteria: Patients whose hemodialysis changes for any reason and the duration (change in hemodialysis pattern). Patients with fever and chills Death, travel or transfer of patients to other medical centers Lack of willingness of patients to continue cooperation
Age	From 18 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	First samples will be selected by convenience method according to inclusion and exclusion criteria. Then random assignment will be used with permuted blocking. R Software will be used to get the blocks. The blocks are made up of 4 English letters (A,B,C,D). A ,B will be considered for the intervention group, and other three letters (C, D) will be considered for the control group. The blocks will be randomly selected in blindfolded manner. Each block will determine the order of entry in the intervention and control groups. Assuming choosing the DACB block means from left hand, first and third, respectively, will be located in the control group, and the second and fourth of participants will be located in the intervention group, respectively.
Blinding (investigator's opinion)	Single blinded
Blinding description	Dialysis patients are unaware of the classification of the intervention and control group.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees
<u>1</u>
Ethics committee
Name of ethics committee Kermanshah university of medical sciences
Street address Department2, SHahid beheshty street
City kermanshah
Province Kermanshah
Postal code 6632546412512
Approval date 2020-05-11, 1399/02/22
Ethics committee reference number ir.kums.rec.1399.180

Health conditions studied
<u>1</u>
Description of health condition studied End stage kidney disease
ICD-10 code N18.5
ICD-10 code description End stage kidney disease

Primary outcomes
<u>1</u>
Description Nausea
Timepoint After three dialysis session
Method of measurement VAS

Secondary outcomes
<u>1</u>
Description temperature
Timepoint Before and after each dialysis session
Method of measurement Mercury thermometer axillary

<u>2</u>
Description Feeling cold and chills
Timepoint During dialysis
Method of measurement Monitoring patient

Intervention groups

1

Description

Intervention group: The temperature of hemodialysis fluid (dialysate) is set at 36 ° C while the type of filter, filter ultrafiltration coefficient, and blood flow rate will not change. Patients in the intervention group will undergo dialysis with cold solution of 36 ° C for 3 times each week for 3-4 hours each time.

Category

Other

2

Description

Control group: The temperature of hemodialysis fluid (dialysate) is set at 37 ° C while the type of filter, filter ultrafiltration coefficient, and blood flow rate will not change. Patients in the control group will undergo dialysis with cold solution of 37 ° C for 3 times each week for 3-4 hours each time.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Kermanshah

Full name of responsible person

yasem arghide

Street address

Kermanshah, Moallem town, end of Roudaki boulevard, Parstar boulevard - Imam Reza (AS) hospital

City

kermanshah

Province

Kermanshah

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Phone

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Email

info @ irhk.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Shahid Beheshti Blvd., Building No. 2, Deputy of Research and Technology

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Fax

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farid_n32@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Kermanshah University of Medical Sciences Vice Chancellor for Research and Technology

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

Kermanshah University of Medical Sciences

Full name of responsible person

Yasem Arghide

Position

Senior Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Kermanshah - Isar Square - Dolatabad - School of Nursing and Midwifery

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Kermanshah

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6715847141

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arghideyasem@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Aliakbar Vaisi-Raygani

Position

Head of the School of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Yasem Arghideh

Position

Senior Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

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Province

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Email

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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

1- Study protocol 2- Study results

When the data will become available and for how long

After completing the study

To whom data/document is available

1- Faculty members 2- Clinical nurses 3- Medical and nursing students

Under which criteria data/document could be used

Access to data or documentation is possible for the following conditions: 1- Use in future study resources 2- Future studies

From where data/document is obtainable

Please contact Yassem Arghideh Email: arghideyasem@yahoo.com

What processes are involved for a request to access data/document

After sending the email to Yassem Arghideh, the email will be answered as soon as possible

Comments