

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of using cold dialysis solution on Subjective Hemodialysis Adequacy, sleep quality and Physiological variables during hemodialysis in patients with End-Stage Renal Disease (ESRD)

Protocol summary

Study aim

The effect of using cold dialysis solution on Subjective Hemodialysis Adequacy, sleep quality and Physiological variables during hemodialysis in patients with End-Stage Renal Disease (ESRD)

Design

The current research is a randomized controlled clinical trial study with a pretest-posttest design (40 people in each group).

Settings and conduct

The samples will be selected from the patients referring to the dialysis ward of Baqiyatollah and Mofarrah hospitals. The patients will be first selected in accordance with the inclusion criteria; then, after obtaining written consent from the patients and introducing and explaining the objectives to the research units by the researcher, the samples will be divided into two intervention and control groups of 40 people by simple random allocation. The present research will be a single-blind study. The blinded group in the present research will be the patients participating in the study. The control group will receive hemodialysis with a temperature of 37°C and the experimental group will receive hemodialysis with a temperature of 35°C.

Participants/Inclusion and exclusion criteria

Over 18 years of age. Performing hemodialysis at least twice a week. Absence of physical or mental disability. Full consciousness and ability to hear and speak to answer questions. Lack of mental or emotional disorders that prohibit effective communication. Hemoglobin level > 8 mg/dL Lack of endocrine disorders (hypothyroidism and hyperparathyroidism) Lack of concurrent malignancy

Intervention groups

In order to conduct the present study, patients in the control group will be hemodialyzed for 4 weeks with standard hemodialysis (37°C) and in the intervention group for 4 weeks with cold hemodialysis (35°C).

Main outcome variables

Quality of sleep , Subjective Adequacy and physiological indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230521058244N1**

Registration date: **2023-09-13, 1402/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-13, 1402/06/22**

Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Ali Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4790 2200

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hosseinzadeh.ah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using cold dialysis solution on Subjective Hemodialysis Adequacy, sleep quality and Physiological variables during hemodialysis in patients with End-Stage Renal Disease (ESRD)

Public title

The effect of cold dialysis solution in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Performing hemodialysis at least twice a week Over 18 years of age Full consciousness and ability to hear and speak to answer questions Hemoglobin level > 8 mg/dL

Exclusion criteria:

Presence of concurrent malignancy Endocrine disorders (hypothyroidism and hyperparathyroidism) Patients with acute mental and physical problems (such as divorce, death of a loved one, financial problems, and developing new chronic disease) Getting an active infection in the body (such as a cold and other infectious diseases)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present research, the samples will be first selected using the convenience sampling method from hemodialysis patients (confirmed by a nephrologist) meeting the inclusion criteria; then, they will be randomly assigned to two intervention and control groups in such a way that some envelopes containing cards labeled M and C will be prepared and the participants will be asked to randomly choose one of the envelopes. The individuals who take the M card will be assigned to the intervention group, and those who take the C card will be assigned to the control group. Thus, the sampling will continue until reaching the determined sample size

Blinding (investigator's opinion)

Single blinded

Blinding description

The current research will be a single-blind study. The blinded group will be the patients participating in the study. The blinding will be performed in this way: The patients will receive the type of hemodialysis considered

for them (both groups of patients receiving cold hemodialysis and conventional hemodialysis) in sealed coded envelopes without having any information about the type of hemodialysis, and considering the gradual decrease in the temperature of hemodialysis, the experimental group patients will not notice the temperature change.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Baqiyatallah Hospital

Street address

MollaSadra street , Vanak Square , Tehran

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Tehran

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Postal code

1435915371

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.028

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

patients with End-Stage Renal Disease (ESRD)

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

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

Subjective Hemodialysis Adequacy score of patients with with End-Stage Renal Disease in Subjective Hemodialysis Adequacy Questionnaire designed and psychometrically evaluated by Bi Niaz et al

Timepoint

before intervention and at the end of the intervention

Method of measurement

Subjective Hemodialysis Adequacy Questionnaire designed and psychometrically evaluated by Bi Niaz et al

2

Description

Richard Campbell sleep quality score of patients with with End-Stage Renal Disease

Timepoint

before intervention and at the end of the intervention

Method of measurement

"Richard Campbell sleep quality questionnaire"

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receive cold hemodialysis . The device temperature will be kept at 35°C for 4 weeks.

Category

Treatment - Devices

2

Description

Control group: Patients receiving normal hemodialysis with a temperature of 37

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Position

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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