

# 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)

##### Phone

+98 21 4790 2200

##### Email address

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

**City**

Tehran

**Province**

Tehran

**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

Ali hosseinzadeh

##### Street address

MollaSadra street , Vanak Square , Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1435915371

##### Phone

+98 21 8804 0060

##### Email

Info@bmsu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Mofarah general hospital

##### Full name of responsible person

Ali hosseinzadeh

##### Street address

Yakhchiabad, Tendgoyan highway, Basir bridge,

Bahmanyar square, Bahmani street

##### City

Tehran

##### Province

Tehran

##### Postal code

1891938911

##### Phone

+98 21 9132 0002

##### Fax

+98 21 9132 2960

##### Email

info@mofarahhospital.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bagheiat-allah University of Medical Sciences

##### Full name of responsible person

Abbas Ali Imani Fuladi

##### Street address

MollaSadra street , Vanak Square , Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1435915371

##### Phone

+98 21 8804 0060

##### Email

Info@bmsu.ac.ir

#### 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

alihosseinzadeh

##### Position

Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
MollaSadra street , Vanak Square , Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1435915371  
**Phone**  
+98 21 8804 0060  
**Email**  
hosseinzadeh.ah@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Abolfazl Rahimi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
MollaSadra street , Vanak Square , Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1435915371  
**Phone**  
+98 21 8804 0060  
**Email**  
fazel123@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Alihosseinzadeh  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
MollaSadra street , Vanak Square , Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1435915371  
**Phone**  
+98 21 8840 0060  
**Email**  
Hosseinzadeh.ah@gmail.com

## 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