

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study the effect of cool dialysate on the sleep quality and post dialysis fatigue degree in patient undergoing hemodialysis

#### Protocol summary

##### Summary

Purpose of the study: The purpose of this study is to evaluate the effect of cool dialysate on the sleep quality and post dialysis fatigue in patients undergoing hemodialysis in the hospitals of Mashhad. Method: This single blinded clinical trial was conducted on two independent groups. Sixty participants from Imam Reza, Montaserieh, Hevdahe Shahrvivar hemodialysis units were recruited through convenience or a non-probability sampling. Then the participants were divided into two groups: a control and an experimental group. Inclusion criteria of study is having some degrees of sleep disturbance and fatigue, having a hemoglobin level >8md/dl. exclusion criteria of study include having an incidence of hemodynamic complications during the intervention sessions; and kidney transplantation. The control group received a dialysis treatment with dialysate at 37°C and experimental group received a hemodialysis treatment with diaysiate at 35°C, the intervention were carried out for 4 weeks. The data were collected through the self-report PFS and PSQI standard questionnaires at the end of each week.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017030432862N1**

Registration date: **2017-08-13, 1396/05/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-13, 1396/05/22

##### Registrant information

**Name**

Fatemeh Salahshourniat

##### Name of organization / entity

Mashhad University of Medical Sciences-  
Nursing&midwifery univercity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3521 3615

##### Email address

salahshournf1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2017-02-18, 1395/11/30

##### Expected recruitment end date

2017-06-07, 1396/03/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study the effect of cool dialysate on the sleep quality and post dialysis fatigue degree in patient undergoing hemodialysis

##### Public title

The effect of cool dialysate on the sleep and fatigue in patient undergoing hemodialysis treatments

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: having a written consent for participation in the study; being between the age of 18-70; having some degrees of sleep disturbance and fatigue based on the questionnaire; undergoing a dialysis

treatment twice or three times a week; undergoing a hemodialysis treatment for at least 6 months; having no experience of participating in similar research; having a hemoglobin level >10md/dl; having no history of crisis in the last 6 months; having no history of mental disease such as major depression; having no history of using depressants; having no history of active cancer; and severe infection. Exclusion criteria: having an incidence of severe crisis; being diagnosed with incurable diseases such as cancer; kidney transplantation at the time of the study; having no incidence of hemodynamic complications during the most of dialysis sessions; unwillingness to continue participating in the study.

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Mashhad University Of Medical Sciences

###### Street address

Qureishi building, Daneshgah street, Mashhad, Khorasan razavi province

###### City

Mashhad

###### Postal code

00985138591511

##### Approval date

2017-01-07, 1395/10/18

##### Ethics committee reference number

IR.MUMS.REC.1395.490

### Health conditions studied

#### 1

##### Description of health condition studied

Chronic kidney disease, stage 5

##### ICD-10 code

n.18.5

##### ICD-10 code description

Chronic kidney disease, stage 5

### Primary outcomes

#### 1

##### Description

Sleep quality and post dialysis fatigue

##### Timepoint

once before the study, 3 times during intervention and 1 after ending the intervention

##### Method of measurement

questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Doing dialysis with 35 ° C dialysate in experimental group

##### Category

Prevention

#### 2

##### Description

Doing dialysis with 37 ° C dialysate in control group

##### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Imam reza hospital

###### Full name of responsible person

Safavi-Zohreh

###### Street address

Ebn sina -street

###### City

Mashhad

### Sponsors / Funding sources

#### 1

##### Sponsor

Name of organization / entity

Vice chancellor for research and technology of  
Mashhad University of Medical Sciences

**Full name of responsible person**

Tafaghodi mohsen

**Street address**

Ghoreyshi Building, Daneshgah Stresst

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research and technology of Mashhad  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Salahshourniat Fathemeh

**Position**

Nurse

**Other areas of specialty/work**

**Street address**

Hemodialysis unit, Imam reza hospital, Ebne sina  
street

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3623 5102

**Fax**

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salahshournf1@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Chamanzari Hamid

**Position**

MS degree

**Other areas of specialty/work**

**Street address**

Nursing and midwifery university, Doctora cross roads,  
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## Person responsible for updating data

**Contact**

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Mashhad University of Medical Sciences

**Full name of responsible person**

Salahshourniat Fatemeh

**Position**

Bachelor of nursing

**Other areas of specialty/work**

**Street address**

Dialysis unit, Imam reza hospital, Ebne sina street

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*