

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 Shahrivar 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

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Phone

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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

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Hemodialysis unit, Imam reza hospital, Ebne sina
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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

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Person responsible for updating data

Contact

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Salahshourniat Fatemeh

Position

Bachelor of nursing

Other areas of specialty/work

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chamanzariah@mums.ac.ir

Web page address

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