

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effects of cool dialysate on sleep quality in patients undergoing hemodialysis

Protocol summary

Summary

Purpose of the study: The purpose of this study was to evaluate the effect of cool dialysate on sleep quality of patients with chronic renal failure undergoing hemodialysis. Design: The study was a randomized single blind controlled clinical trial, done in the before and after treatment method. Methodology: Population: The study will be done on hemodialysis patients who go to dialysis ward of vasei hospital in sabzevar. After determining patients with sleep disorders, individuals are selected based on inclusion criteria. Inclusion criteria are Being on dialysis weekly list and do it two or three times a week and every three or four hours, Patients who have received score higher than 5 Pittsburgh Sleep Quality Index. and Having a history of at least six months hemodialysis. Exclusion criteria included acute complications (cardiac, respiratory arrest, Disequilibrium syndrome) and the lack of cold tolerance and the patient's unwillingness to continue to participate in the study. Interventions: The study will be done on 13 patients in the intervention group and 13 patients in the control group who had the inclusion criteria and were randomly divided. Blinding will be imposed on patients in both groups of this study. For four week, all patients in both groups will get hemodialysis with dialysis solution with standard temperature (37 ° C). Then, At the end of 12 hemodialysis will be completed by researcher Pittsburgh Sleep Quality Index for each of them. for four week, the experimental group will get hemodialysis with cold dialysis solution with temperature (35.5 ° C) and the control group will get hemodialysis with dialysis solution with standard temperature (37 ° C). Then, At the end of 12 hemodialysis will be completed by researcher Pittsburgh Sleep Quality Index for each of them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060228219N1**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Roghayeh Ghanbarabadi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4522 1838

Email address

ghanbarabadi93@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of cool dialysate on sleep quality in patients undergoing hemodialysis

Public title

Effects of cool dialysate on sleep quality in patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: consent for participation in the study; Age older than 18 years and maximum 75 years; suffering from vision, hearing loss; not suffering from clear mental disorders and severe emotional mood disorders, which prevent effective communication; Patients with chronic renal failure (patients who 6 months have passed since their dialysis); Patients receiving dialysis treatment three times a week and each session for 4 hours; not suffering from endocrine disorders (such as hypothyroidism, hyperparathyroidism; Patients who have received score higher than 5 Pittsburgh Sleep Quality Index; Patients with hemoglobin levels are greater than 8 mg dl; Lack of debilitating diseases and disorders such as severe chronic heart, respiratory, hepatic, history of seizures and severe neuropathy based on medical records and patient history; Lack of psychiatric disorders (schizophrenia, anxiety, depression) or dementia Or stay in psychiatric wards because of the items listed; No history of kidney transplant; Exclusion criteria: Patients who develop acute complications during hemodialysis (Disequilibrium syndrome - embolism - dysrhythmia - cardiac, respiratory arrest - Coma -); patients who discontinued they dialysis for any reason; Patients who are referred for kidney transplants (Patients who get kidney transplantation during the study); the patient's death, patients who cannot tolerate cold dialysis; the patient's unwillingness to continue to participate in the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

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**

Sabzevar University of Medical Sciences

Street address

Building Number two,Vice Chancellor for Education,Sabzevar University of Medical Sciences and Health

City

sabzevar

Postal code

0098514446070

Approval date

2016-07-14, 1395/04/24

Ethics committee reference number

ir.medsab.rec.1395.57

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

Chronic renal failure

ICD-10 code

N18.5

ICD-10 code description

End stage kidney disease:on dialysis

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

sleep quality

Timepoint

Before, during and after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention/Control 1 CONTROL: temperature of hemodialysis fluid (dialysate) is regulated on 37 ° C . Type of filter, coefficient of ultra-filtration, blood flow rate and type of apparatus are constant during the study. Intervention/Control 2 intervention: temperature of hemodialysis fluid is regulated on (35.5 ° C) and type of filter, coefficient of ultra-filtration, blood flow rate are not changed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

vasei hospital in sa bzevar

Full name of responsible person

Dr zahra mir hosyni

Street address

sabzevar

City

sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Musa Al-Reza Taday'oun far

Street address

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Services

City

sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Roghayyeh ghanbarabadi

Position

Nursing Graduate Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Statistical Analysis Plan

Data Dictionary

empty