Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Roghayeh Ghanbarabadi
Name of organization / entity
Sabzevar University of Medical Sciences
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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
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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
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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
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Building number two, Vice Chancellor for Education, Sabzevar University of Medical Sciences and Health Services
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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
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
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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