Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of cool dialysate on pruritus during hemodialysis in patients with chronic renal failure

Protocol summary

Summary

Purpose of the study:The purpose of this study was to evaluate the effect of cool dialysate on itching status of patients with chronic renal failure hemodialysis during hemodialysis. This is an easy method of treatment, without any cost, available, and without complications. Design: The study was a randomized triple 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 Imam Reza hospital in Mashhad. After determining patients with pruritus, individuals are selected based on inclusion criteria. Inclusion criteria are history of itching during dialysis, during the last 2 months and lack of skin problems and anemia. Exclusion criteria included acute complications (cardiac, respiratory arrest, Disequilibrium syndrome) and the lack of cold tolerance. Interventions: The study will be done on 30 patients in the intervention group and 30 patients in the control group who had the inclusion criteria and were randomly divided. Blinding will be imposed on patients in both groups and researchers and statistical analyst of this study. For one week, all patients in both groups will get hemodialysis with dialysis solution with standard temperature (37 ° C). Then, for one 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). We will analyze and record the itch status of patients during hemodialysis with a questionnaire, in both groups, before and after the intervention, and the results of both groups will be analyzed using statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120920260N1**

Registration date: **2015-04-01, 1394/01/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-01, 1394/01/12

Registrant information

Name

Elaheh Jaghouri

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 514446070

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Sabzevar University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cool dialysate on pruritus during hemodialysis in patients with chronic renal failure

Public title
The effect of cool dialysate on pruritus in patients with chronic renal failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: consent for participation in the study; Age older than 18 years and maximum 65 years; suffering from vision, hearing loss (deafness and dumbness); not suffering from clear mental disorders and severe emotional mood disorders, which prevent effective communication; Patients with chronic renal failure (patients who 3 months have passed since their dialysis); patients who have Arteriovenous fistulas for hemodialysis; Patients receiving dialysis treatment three times a week and each session for 4 hours; patients who over the past 2 months, have a history of itching during hemodialysis; not suffering from endocrine disorders (such as hypothyroidism, hyperparathyroidism; not suffering from febrile illnesses (pneumonia, colds); No history of pruritic skin diseases; No use of medications or foods, causing itching; Lack of pregnancy and liver problems; Patients with a KT / V ≥1; Patients with hemoglobin of 10-11 mg / dl Exclusion criteria: Patients who develop acute complications during hemodialysis (Disequilibrium syndrome - embolism - dysrhythmia – cardiac, respiratory arrest - Coma -); Patients who suffer from skin disorders that lead to the itch (Scabies - psoriasis); patients who discontinued they dialysis for any reason; Patients who are referred for kidney transplants (Patients who get kidney transplantation during the study); Change in the frequency of hemodialysis, the patient's death, patients who cannot tolerate cold dialysis; woman patients who become pregnant, hemodialysis with acetate, the incidence of fever, the patient's unwillingness to continue to participate in the study.
Age
From **18 years** old to **65 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)
Triple 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
0098571446070
Approval date
2014-12-29, 1393/10/08
Ethics committee reference number
3/108/ک ژ پ

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
Pruritus
Timepoint
Before, during and after intervention
Method of measurement
Vas-scale assessment and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
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.
Category
Other

2

Description
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
Imam Reza Hospital in Mashhad
Full name of responsible person
Dr Farzaneh Sharifi Pour
Street address
Imam Reza Hospital in Mashhad
City
Mashhad

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
Building number two, Vice Chancellor for Education, Sabzevar University of Medical Sciences and Health 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
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Person responsible for updating data

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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