

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 514446070

Email address

jaghorie1@mums.ac.ir

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 $KT/V \geq 1$; 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

ک ژ پ/3/108

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

Full name of responsible person

Elaheh Jaghouri

Position

Nursing Graduate Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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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