

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of hemodialysis fluid cooling on quality of sleep, uremic pruritus and hemodialysis efficiency in patients who are treated with hemodialysis in Semnan.

Protocol summary

Summary

The aim of this study is to survey effect of cooling hemodialysis fluid on sleep quality, uremic pruritus and hemodialysis efficiency. All of the patients referred to hemodialysis center in Semnan city who treated with hemodialysis more than 6 months, dialysis three times per week for four hours, and who have not any acute disorders were selected as sample. At first, these patients are treated with 37 centigrade hemodialysis fluid for four weeks. Then the same patients are treated four weeks with 35 centigrade hemodialysis fluid and the same setting of apparatus and type of filter. Sleep quality, uremic pruritus, and hemodialysis efficiency were be compared in two stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203316481N3**

Registration date: **2012-04-09, 1391/01/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-04-09, 1391/01/21

Registrant information

Name

Mohsen Soleimani

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 23 3365 4190

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solli257@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of hemodialysis fluid cooling on quality of sleep, uremic pruritus and hemodialysis efficiency in patients who are treated with hemodialysis in Semnan.

Public title

Evaluation the effect of hemodialysis fluid cooling on sleep, pruritus and hemodialysis efficiency in patients with hemodialysis.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Patients who have arteriovenous fistula for hemodialysis 2. Patients with constant blood flow rate during hemodialysis in control and test stages 3. Patients who have similar filter type and equal filter ultra-filtration coefficient during control and test stage. 4. Patients with hemodialysis three times a week and each time four hours. 5. Patients with hemodialysis at least 6 months before. Exclusion criteria: 1- Patients with

acute disease. 2-Patients with skin disorders that cause the itching. 3-Patients with skin allergy symptoms. 4- Patients who are treated with anti-itching drugs 5- Patients who stop hemodialysis related to any causes 6- Patients who are referred to renal transplantation 7- Patients with acute renal failure 8-Change in frequency of hemodialysis 9-Patients receive NSAID drugs such as Acetaminophen 10-Patients with psychotic disorders 11- Patients with psychosomatic disorders and receive with drugs that affect in sleep. 12-Hemodialysis with acetate fluid.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 35

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

At first the patients are in control group and then in test group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Semnan, Iran.

City

Semnan

Postal code

3513138111

Approval date

2012-03-10, 1390/12/20

Ethics committee reference number

A-10-18-4.713

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

Patients who are treated with hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Renal Failure

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

Sleep Quality

Timepoint

Weekly

Method of measurement

Pittsburgh Sleep Quality Index

2**Description**

Uremic pruritus

Timepoint

Weekly

Method of measurement

Pruritus score

3**Description**

Hemodialysis efficiency

Timepoint

Weekly

Method of measurement

Urea Reduction Ratio

Secondary outcomes

empty

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

Stage 1: temperature of hemodialysis fluid (dialysate) is regulated on 37 degree of Celsius. Type of filter, coefficient of ultra-filtration, blood flow rate and type of apparatus are constant during the study.

Category

Treatment - Other

2**Description**

Stage 2: temperature of hemodialysis fluid is regulated on 35 degree of Celsius and type of filter, coefficient of ultra-filtration, blood flow rate are not changed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Semnan

Full name of responsible person

Mohsen Soleimani

Street address

Nursing faculty and Allied Health, Semnan University of Medical Sciences, Semnan.

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Raheb Ghorbani

Street address

Vice Chancellor for Research, Semnan University of Medical Sciences, Basij Avenue, Semnan.

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mohsen Soleimani

Position

Ph.D

Other areas of specialty/work

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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