

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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)

##### Phone

+98 23 3365 4190

##### Email address

soli257@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**

**Street address**

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

**City**

Semnan

**Postal code**

3513138111

**Phone**

+98 23 1335 4191

**Fax**

**Email**

soli257@yahoo.com

**Web page address**

## Person responsible for scientific 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**

**Street address**

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

**City**

Semnan

**Postal code**

3513138111

**Phone**

+98 23 1335 4191

**Fax**

+98 23 1335 4177

**Email**

Soli257@yahoo.com

**Web page address**

## Person responsible for updating data

### 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**

**Street address**

Nursing Faculty and allied Health, Semnan University of Medical Sciences, Semnan

**City**

Semnan

**Postal code**

3513138111

**Phone**

+98 23 1335 4191

**Fax**

+98 23 1335 4177

**Email**

Soli257@yahoo.com

**Web page address**

## **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*