

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of Cool Dialysate on Restless Leg Syndrome (RLS) in Patients Treated with Hemodialysis

#### Protocol summary

##### Study aim

The effect of cold dialysis solution on Restless Leg Syndrome in patients undergoing hemodialysis. This study is an easy, cost-free, affordable and unprotected treatment.

##### Design

In this study 63 patients with restless leg syndrome who are referred to the hemodialysis centers are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

##### Settings and conduct

This study will be performed on 32 patients in the experimental group and 31 patients in the control group who have inclusion criteria and will randomly be divided into two groups. In this study, patients, researcher and data analyst will be blinded. For one week, all patients will undergo hemodialysis with standardized dialysis solution (37 ° C) then the test group will be treated with a cold hemodialysis solution at 35.5 ° C and control group with a standard temperature (37 ° C) for one month. Patients in both groups will be evaluated before and after intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The history of Restless Leg Syndrome during dialysis over the past 2 months. 2. No drug or food use that exacerbate the syndrome during dialysis  
Exclusion criteria: 1. Patients who will refer for renal transplantation (patients who are linked during the study) 2. Cases of chronic infections, heart failure, chronic pulmonary disease, severe anemia, coronary artery disease and drug abuse

##### Intervention groups

The effectiveness of dialysis solution at 35.5 ° C on 62 patients (intervention) versus patients who are dialysed with routine fluid solution (control)

##### Main outcome variables

1- Restless leg syndrom 2- C-Reactive Protein

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170722035232N1**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

##### Registration date

2018-02-10, 1396/11/21

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4422 6989

##### Email address

kashanie94@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-14, 1396/11/25

##### Expected recruitment end date

2018-03-30, 1397/01/10

##### Actual recruitment start date

2018-01-21, 1396/11/01

##### Actual recruitment end date

2018-04-04, 1397/01/15

##### Trial completion date

empty

##### Scientific title

The Effects of Cool Dialysate on Restless Leg Syndrome

(RLS) in Patients Treated with Hemodialysis

**Public title**

The Effect of Cool Dialysis on Restless Leg Syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Informed consent to participate in the study Full consciousness and acceptable verbal and auditory ability to answer the questions The patient should not suffer from obvious mental disorder and severe mood - emotional disturbance that prevents effective communication The patient should be in normal neurological and vascular status. Lack of muscular and skeletal disorders debilitating physical activity Lack of ulcer and redness in limbs Patients with chronic renal failure (Patients who have been undergoing hemodialysis for 3 months). Patients who have an arteriovenous fistula, permanent catheter and arterial-venous graft can access their vessels. Patients undergoing hemodialysis three times a week and 4 hours each session. Patients who have had a history of restless leg syndrome during the past 2 months of hemodialysis. Lack of endocrine disorders (such as hypothyroidism and hyperparathyroidism). No history of itchy skin diseases Do not use medicines or foods that they exacerbate the leg syndrome during dialysis, such as: neuroleptics, triangular antidepressants, diphenhydramine, caffeine, alcohol, lithium, beta-blockers, selective serotonin reuptake inhibitors, and serotonin-norepinephrine reuptake inhibitors. Lack of liver problems No medication or treatments that affect on restless leg syndrome during dialysis(oral medicines, complementary medicine, acupuncture and topical softeners). Patients with  $KT / V \geq 1$  Patients with hemoglobin 10-11 mg / dL. Lack of febrile illness and chronic infections (pneumonia, cold during hemodialysis). Use of bicarbonate dialysis solution

**Exclusion criteria:**

Patients with catabolic processes such as: malignancies Diabetic neuropathy Cases of chronic infections, heart failure, chronic pulmonary disease, severe anemia, coronary artery disease and drug abuse

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **60**

Actual sample size reached: **63**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be selected using available sampling method and they will take place in intervention and

control groups using random allocation permutations blocks.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, Patients in both groups will be blinded by a paper cover that is placed on the dialysis temperature display. The researcher will be blinded by completing the questionnaires by researcher assistant. And data analyzers will be blinded by patient encoding.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Sabzevar University of Medical Sciences

**Street address**

No. 293, Ibn Yemin No. 41, Ibn Yemin Street

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613876481

**Approval date**

2016-12-05, 1395/09/15

**Ethics committee reference number**

IR.Medsab.Rec.1395.92

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

Restless Leg Syndrome

**ICD-10 code**

G25.81

**ICD-10 code description**

Restless legs syndrome

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

Restless leg syndrome

**Timepoint**

Before and during and after the intervention

**Method of measurement**

International Restless Legs Syndrome Study Group

Questionnaire

## Secondary outcomes

### 1

#### Description

Measuring C-Reactive Protein (CRP)

#### Timepoint

Before the intervention and after the intervention

#### Method of measurement

Use of CRP kits made by Company QCA Spain

## Intervention groups

### 1

#### Description

Intervention group: The hemodialysis fluid temperature (dialysate) will be adjusted to 35.5 ° C, while the filter type, the ratio of ultrafiltration of the filter, and the speed of the blood flow will not be changed.

#### Category

Treatment - Other

### 2

#### Description

Control group: Hemodialysis fluid temperature will be set at 37 ° C, while the filter type, the ratio of ultrafiltration of the filter, and the speed of the blood flow, and type of device during the study will be fixed.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Vasei hospital

##### Full name of responsible person

Ehsan Kashani

##### Street address

Vasei Medical Education Center, Keshavarz Blvd

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617747431

##### Phone

+98 51 4465 1300

##### Fax

+98 51 4465 3867

##### Email

KashaniE94@Medsab.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Kashefi Dialysis Center

##### Full name of responsible person

Ehsan Kashani

##### Street address

Kashefi Dialysis Center, Kashefi Ave

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617747431

##### Phone

+98 51 4465 1300

##### Fax

+98 51 4465 3867

##### Email

KashaniE94@Medsab.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mr. Mohsen Koushan

##### Street address

Pardis of Sabzevar University of Medical Sciences, higher than the Shohada Gomnam, Towhid Boulevard

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

##### Phone

+98 51 4401 8300

##### Email

mkoushan@yahoo.com

#### 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

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Ehsan Kashani

**Position**

Master's degree nursing specialist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Pardis of Sabzevar University of Medical Sciences,  
above the Yadbood of Shohada Gomnam, Boulevard  
of Tohid

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+98 51 4401 8300

**Email**

KashaniE94@Medsab.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mr. Dr. Mostafa Rad

**Position**

Ph.D. Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Pardis of Sabzevar University of Medical Sciences,  
above the Yadbood of Shohada Gomnam, Boulevard  
of Tohid

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+98 51 4401 8300

**Email**

mostafarad633@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Ehsan Kashani

**Position**

Nursing Graduate Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Pardis of Sabzevar University of Medical Sciences,  
above the Yadbood of Shohada Gomnam, Towhid  
Boulevard

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+98 51 4401 8300

**Email**

KashaniE94@Medsab.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available