

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

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KashaniE94@Medsab.ac.ir

2

Recruitment center

Name of recruitment center

Kashefi Dialysis Center

Full name of responsible person

Ehsan Kashani

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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

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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

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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

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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

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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