

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of cool dialysate and stretching exercises on restless leg syndrome in patients undergoing hemodialysis with chronic renal failure

Protocol summary

Study aim

Comparison the effect of cool dialysate and stretching exercises on restless leg syndrome in patients undergoing hemodialysis with chronic renal failure

Design

Sixty patients with restless leg syndrome are randomly assigned into two groups of cold-dialysis solution and stretching exercises. A study is a double-blind clinical trial with parallel groups.

Settings and conduct

This study will be performed on 30 patients in the experimental group and 30 patients in the control group in the dialysis section at Sabzevar Hospital who have inclusion criteria and will randomly be divided into two groups. In this study, researcher and data analyst will be blinded. For 6 weeks, the experimental group is dialyzed at 35.5 ° C and the control group performs stretching exercises. The restless leg syndrome in both groups will be evaluated with the International restless leg syndrome questionnaire before intervention and at the end of each week

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patient diagnosed with chronic renal failure who has been undergoing hemodialysis for 3 months. 2. Patients with a minimum hemoglobin of 10 mg / dL Exclusion criteria: 1. Hearing and visual impairment 2) Taking medication or food that exacerbates restless leg syndrome during dialysis

Intervention groups

Intervention group 1: Among patients with restless leg syndrome, a group of 30 patients is selected as the cold dialysis solution group. And they will undergo cold hemodialysis (35.5 ° C) 4 hours at each session, for 6 weeks 3 times a week. Intervention group 2: Among patients with restless leg syndrome, 30 patients undergo stretching exercises and for 6 weeks 3 times a week for half an hour in the first 2 hours of dialysis do stretching

exercises. The dialysis temperature for the group is the same as the standard solution temperature (37 ° C).

Main outcome variables

Restless legs syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181108041594N1**

Registration date: **2019-01-04, 1397/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-04, 1397/10/14**

Update count: **0**

Registration date

2019-01-04, 1397/10/14

Registrant information

Name

Azam Zirkaliabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-07, 1397/09/16

Expected recruitment end date

2019-01-17, 1397/10/27

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of cool dialysate and stretching exercises on restless leg syndrome in patients undergoing hemodialysis with chronic renal failure

Public title
Comparison the effect of cool dialysate and stretching exercises on restless leg syndrome in dialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to participate in the study Age over 18 and up to 71 years Patients with a minimum hemoglobin of 10 mg / dL Patient diagnosed with chronic renal failure who has been undergoing hemodialysis for 3 months Patients with arteriovenous fistula for hemodialysis Patients undergoing hemodialysis three times a week and each session are 4 hours Patients who have had Hemodialysis over the past 2 months have had a history of restless leg syndrome during Hemodialysis Patients with adequacy of dialysis more or equal 1
Exclusion criteria:
Hearing and visual impairment Taking medication or food that exacerbates restless leg syndrome during dialysis Pregnancy and the presence of liver problems Receiving treatments that are effective on restless leg syndrome during dialysis (complementary medicine, acupuncture and topical conditioners) The presence of any infection and ulcers in the legs Having orthopedic problems Having vascular problems in the lower extremities Severe mental illness and mood disorder - severe emotional disturbance that prevents effective communication. Patient with hypercalcemia and hypocalcemia

Age
From **18 years** old to **71 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are selected according to the eligibility criteria and then they randomly are assigned in two groups with 30 patients, the stretching exercises group (by performing hemodialysis with dialysis solution temperature 37) and cold dialysate group (performing hemodialysis with dialysis solution 35/5) using the

Permutation blocks method. The control group is marked with the letter a and the intervention group with the letter b and the size of each block is 4, and the number of blocks is 15 and the number of possible permutations is 4. Then from the random number table or using the simulation command in the application R (runif(15,min=1,max=4), fifteen random numbers selected and fill 15 blocks of states. So the first four person who enter the study the first person receiving treatment b, the second treatment a, the third person receiving treatment b, and the fourth person receiving treatment a. second Four person who enter the study the first person receiving treatment b, the second treatment b, the third person receiving treatment a, and the fourth person receiving treatment a. Fifteenth four person who enter the study the first person receiving treatment b, the second treatment a, the third person receiving treatment b, and the fourth person receiving treatment a. In this study Patients are not blind. The researcher will be blinded by completing the questionnaires by researcher assistant. And data analyzers will be blinded by patient encoding. .

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study Patients are not blind. 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

Block B, Pardis of Sabzevar University of Medical Sciences, Road Tohid Shahr

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Sabzevar

Province

Razavi Khorasan

Postal code

94617-85493

Approval date

2018-11-11, 1397/08/20

Ethics committee reference number

IR.MEDSAB.REC.1397.056

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 legs syndrome

Timepoint

The measurements of restless leg syndrome are at the beginning of the study before the start of the intervention and then at the end of each week after the completion of the dialysis for 6 weeks.

Method of measurement

The severity of restless leg syndrome questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Among patients with restless leg syndrome, a group of 30 patients is selected as the cold dialysis solution group. And they will undergo cold hemodialysis (35.5 ° C) 4 hours at each session, for 6 weeks.

Category

Treatment - Other

2

Description

Intervention group 2: Among patients with restless leg syndrome, 30 patients undergo stretching exercises and for 6 weeks 3 times a week for half an hour in the first 2 hours of dialysis, stretching exercises including pelvic to the sides, Quadriceps muscle stretching, stretching of the muscle of the gluteal muscle , Pulling the hamstrings and pulling the knee to the chest. The dialysis temperature for the group is the same as the standard solution temperature (37 ° C).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Vasei Hospital in Sabzevar

Full name of responsible person

Mostafa Rad

Street address

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

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Ghorat

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

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Email

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Web page address

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

Mostafa Rad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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