Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 hemodialysyis (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 Zirakaliabadi

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

City

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 hemodialysyis (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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr. Fereshteh Ghorat
Street address
Pardis of Sabzevar University of Medical Sciences, above the Yadbood of Shohada Gomnam, Boulevard of Tohid
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Fax
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info@medsab.ac.ir
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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Latest degree

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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