Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect Of Intradialytic Stretching Exercise On Severity Of Symptoms Of Restless Legs Syndrome And Quality Of Sleep In Hemodialysis Patients

Protocol summary

Summary

Restless legs syndrome (RLS) is a sensorimotor disorder that is characterized by motor restlessness resulting in an uncontrolled urge to move the affected body parts.RLS symptoms often worsen in long sitting and rest, such as prolonged sleep and during dialysis. Generally the symptoms of restless leg syndrome in renal patients is more common and more severe and causing reduced sleep duration, sleep disruption and reduced quality of life. Since the symptoms of this syndrome occurs or gets worse during the period of immobilization, mild exercise such as stretching can relieve symptoms of restless leg syndrome.This study is a clinical trial to evaluate the impact of intradialytic stretching on symptoms of restless leg syndromeand and sleep quality in hemodialysis patients.in Hashemi Nejad hospital in Tehran, Iran. 36 patients will be diagnosed with RLS symptoms as defined by the standard criteria and recruited for being part of the study. The recruited patients will be offered the option to exercise (Ex-group) or not to exercise (Con-group) for the period of 8 weeks. Stretching exercises will be performed 3 times a weeks, 30 minutes each time for the last two hours of dialysis. Sleep quality and restless legs syndrome severity will be assessed using the Pittsburgh Sleep Quality questionnaires and International RLS (IRLS)study group rating scale at baseline, weeks 4 and at the end of the study.

General information

Acronym

Restless Legs Syndrome

IRCT registration information

IRCT registration number: **IRCT201202182226N9**
Registration date: **2012-11-19, 1391/08/29**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-11-19, 1391/08/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Intradialytic Stretching Exercise On Severity Of Symptoms Of Restless Legs Syndrome And Quality Of Sleep In Hemodialysis Patients

Public title

The Effect Of Exercise On Severity Of Symptoms Of Restless Legs Syndrome And Quality Of Sleep In

Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: answering "yes" to the first four questions of the restless leg syndrome questionnaire; age over 18-dialysis; 3 times a week and 3 or 4 hour hemodialysis each time; no mental and physical disabilities; having full awareness; listening and speaking ability; no infection and ulcers in the legs-no orthopedic problems; no peripheral neuropathy or vascular problems in legs; restless leg syndrome confirmed by GP. Exclusion criteria: no exercise for three consecutive sessions and six sessions generally.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee nursing&midwifery Tehran University of Medical Sciences

Street address

squar toohid-nursing&midwifery facultyTehran University of Medical Sciences-tehran-iran

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tehran

Postal code

1419733171

Approval date

2012-09-09, 1391/06/19

Ethics committee reference number

130/1235/د

Health conditions studied

1

Description of health condition studied

Restless legs syndrome

ICD-10 code

G25.8

ICD-10 code description

Other specified extrapyramidal and movement disorders

Primary outcomes

1

Description

Decrease severity of restless leg syndrome symptomes and increase sleep quality after exercise

Timepoint

Before intervention, the end of the 4th week and 8th week

Method of measurement

pittsburgh Questionnaire- International Restless Legs Syndrome Study Group (IRLSSG)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: stretching exercises will be performed three times a week for eight weeks and questionnaires will be completed at the beginning, end of 4th week and 8th week.

Category

Treatment - Other

2

Description

Control group: questionnaires will be completed at the beginning, end of 4th week and 8th week. No intervention for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hashemi Nejad hospital, Tehran University of Medical Sciences

Full name of responsible person

Mansooreh Aliasgarpour

Street address

valinejad st.-squar vanak- valiasr street

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotohi
Street address
Keshavarse bulvar, Ghods street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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