Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A clinical trial of the effect of exercise on the severity of restless legs syndrome in hemodialysis patients

Protocol summary

Summary

The aim of this study was to determine the effects of exercise on the severity of restless legs syndrome in hemodialysis patients in Hajar hospital is 2015. In this clinical trial, 50 cases of hemodialysis patients with restless legs syndrome diagnosed through questionnaire and qualified to enter the study are selected. Exercise schedule requires patients to do pedal biking before the dialysis for one month, 3 times a week, each time for 10 minutes. After the exercise program, dialysis using filters for each group was determined in advance. In order to collect information on participants in the scheme, separate cheklist including age, sex, weight before dialysis, type of filter, pump speed, pressure, duration of work by bike will be prepared and after this period, restless leg syndrome in their checked again. Inclusion criteria included a hemodialysis patient whose last dialysis dates back to at least 6 month ago and not having any disorder of the musculoskeletal system that prevents the desired exercise (pedaling a bicycle) above. Exclusion criteria included patient's inability to exercise, patients opt to participate in the study and the impossibility of continuing the study for various reasons such as changing undergo dialysis or death of the patient.

General information

Acronym

RLS

IRCT registration information

IRCT registration number: **IRCT2016021926643N1**
Registration date: **2016-06-02, 1395/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-02, 1395/03/13

Registrant information

Name

Narges Abaszadeh Dehkordy

Name of organization / entity

Islamic Azad University ، Isfahan unit (Khorasgan)

Country

Iran (Islamic Republic of)

Phone

+98 38 3335 1671

Email address

abaszadeh1393@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-03-01, 1394/12/11

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the effect of exercise on the severity of restless legs syndrome in hemodialysis patients

Public title

The effect of an exercise program on the severity of restless legs syndrome in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included a hemodialysis patient whose last dialysis dates back to at least 6 month ago and not

having any disorder of the musculoskeletal system that prevents the desired exercise (pedaling a bicycle) above. Exclusion criteria included patient's inability to exercise, patients opt to participate in the study and the impossibility of continuing the study for various reasons such as changing undergo dialysis or death of the patient.

Age
To **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Bio-medical research ethics committee of the University of Isfahan University of Medical Sciences

Street address
Isfahan

City
Isfahan

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
IR.NUI.REC.1394.4.130

Health conditions studied

1

Description of health condition studied
Restless Legs Syndrome

ICD-10 code
G25.8

ICD-10 code description
Restless Legs Syndrom

Primary outcomes

1

Description
the severity of restless legs syndrom

Timepoint
before intervention - after intervention

Method of measurement
restless legs syndrom questionnaire

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description
Exercise schedule requires patients to do pedal biking before the dialysis for one month, 3 times a week, each time for 10 minutes. After the exercise program, dialysis using predefined filters is done for each group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahrekord Hajar Hospital

Full name of responsible person
Narges Abaszadeh Dehkordy

Street address
Street Sport

City
Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Investigator

Full name of responsible person
Narges Abaszadeh Dehkordi

Street address

No. 20, Alley 30, Street Sport

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Investigator

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

Contact

Name of organization / entity

Isfahan Azad University(khorasgan)

Full name of responsible person

Narges Abaszadeh Dehkordy

Position

Graduate student medical-surgical nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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