

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 checklist 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

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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 Dehkordi

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)
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Narges Abaszadeh Dehkordy
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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