

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of intradialytic aerobic exercises on restless legs syndrome and quality of life in hemodialytic patients

Protocol summary

Summary

This is a clinical trial carried out in "Azahra", "Noor" and "Ali Asghar" hospitals in Esfahan. Fourteen patients receiving hemodialysis with the following criteria were recruited by simple sampling method: 1. Receiving dialysis for at least 3 months, 2. Existence of characteristic movements of restless leg syndrome, 3. Effective dialysis ($kt/v > 1$)

Exclusion criteria:

- Existence of musculoskeletal disorder that prevents patients from doing the exercise
- Ischemic heart disease. Patients are randomly divided into exercise and control groups. Those in the intervention group receive an exercise schedule of 30 minutes of peddling by Medi-Bike (Swiss made) between the 2nd and 3rd hour of hemodialysis 3 times a week for 16 weeks. The exercise will not commence or will be stopped immediately in the following circumstances: BP $> 180/110$ mmHg or SBP < 90 mmHg, chest pain or dyspnea, signs of inappropriate tissue perfusion, neurological signs such as dizziness or ataxia. The severity of restless legs syndrome and quality of life will be assessed with RLSQ and SF36 questionnaire respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806082370N3**
Registration date: **2010-06-16, 1389/03/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-16, 1389/03/26

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Esfahan University of Medical Sciences

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2009-06-20, 1388/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intradialytic aerobic exercises on restless legs syndrome and quality of life in hemodialytic patients

Public title

The effect of intradialytic aerobic exercises on restless legs syndrome and quality of life in hemodialytic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1. Receiving dialysis for at least 3 months, 2. Existence of characteristic movements of restless leg syndrome, 3. Effective dialysis ($kt/v > 1$)

Exclusion criteria: 1. Existence of musculoskeletal disorder that prevents patients from doing the exercise
2. Ischemic heart disease

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **14**

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**

Isfahan university of medical science

Street address

vice chancellor for research, Isfahan university of medical science

City

Isfahan

Postal code**Approval date**

2017-11-21, 1396/08/30

Ethics committee reference number

387458

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**

Severity of restless legs syndrome

Timepoint

Every two week and then every four week

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Quality of life

Timepoint

At the beginning and the end of study

Method of measurement

Questionnaire

Intervention groups**1****Description**

No intervention

Category

N/A

2**Description**

Those in the intervention group receive an exercise schedule of 30 minutes of peddling by Medi-Bike (Swiss made) between the 2nd and 3rd hour of hemodialysis 3 times a week for 16 weeks

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

"Azahra" and "Noor and Ali Asghar" hospitals in Esfahan

Full name of responsible person**Street address****City**

Esfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research

Street address

Esfahan University of Medical Sciences

City

Esfahan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Contact

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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