

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 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 syndrome 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 week, 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

###### Name

Mansoorh Aliasgharpour

###### Name of organization / entity

Nursing & midwifery faculty, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6693 7120

###### Email address

aliasgha@sina.tums.ac.ir

##### 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

##### City

tehran

##### Postal code

1419733171

#### Approval date

2012-09-09, 1391/06/19

#### Ethics committee reference number

130/1235/3

## 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 symptoms 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

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Zahra Abbasi  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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Faculty member  
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**Web page address**

## 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*