

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of vibration and massage on symptoms of RLS and quality of sleep in hemodialysis patients

Protocol summary

Summary

Restless legs syndrome is a common neurological disorder consisting of an uncomfortable Sensation in one's legs and irresistible urge or desire to move them. This study carries to determine the effect of massage and vibration on severity of symptoms of Restless legs syndrome and quality of sleep in hemodialysis patients. Patients with chronic renal failure undergoing at least 3 months dialysis and normal vasoskeletonneurological status include and comatose patients with catabolic disorders and drugs using history exclude. This randomized clinical trial will be conduct on 80 patients with Restless legs syndrome through cross over design in Hemodialysis wards of Yazd province by applying vibration and massage on patient legs for 12 sessions. We hope to improve Restless legs syndrome symptoms and sleep quality of hemodialysis patients by our interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022826814N1**

Registration date: **2016-07-06, 1395/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-06, 1395/04/16

Registrant information

Name

Somaye Azimpour

Name of organization / entity

Rafsanjan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 936 328 1502

Email address

s.hosseini@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vibration and massage on symptoms of RLS and quality of sleep in hemodialysis patients

Public title

The effect of vibration and massage on symptoms of RLS and quality of sleep in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: affliction with chronic renal failure with at least 3 months of hemodialysis the presence of restless leg syndrome; having a normal neurologic and vascular and coagulate condition; lack of musculo-skeletal disorders; Lack of wounds and infections and skin disease and limb fracture; Be able to participate in the research and collaboration Exclusion criteria: patients with catabolic processes; unconsciousness; taking of analgesics; tranquilizers; narcotics and psychiatric drugs; skin lesions; lack of cooperation

Age
From **15 years** old to **60 years** old
Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Rafsanjan University of Medical Science

Street address
Nursing and Midwifery Faculty

City
Rafsanjan

Postal code

Approval date
2016-01-21, 1394/11/01

Ethics committee reference number
ir.rums.rec.1394.193

Health conditions studied

1

Description of health condition studied
Hemodialysis

ICD-10 code
z49.0

ICD-10 code description
preparatory care for dialysis

Primary outcomes

1

Description

Symptoms severity of Restless Leg Syndrome

Timepoint

One month after interventions

Method of measurement

Restless Leg Syndrome Questionnaires

Secondary outcomes

1

Description

Quality of Sleep

Timepoint

One Month after Interventions

Method of measurement

Petersburg Sleep Quality Questionnaire

Intervention groups

1

Description

vibration for 12 sessions on both shins and calves,
10minutes each time Intervention category

Category

Other

2

Description

massage for 12 sessions on both shins and calves,
10minutes each time Intervention category

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Jafar Sadeq Hospital in Meybod, Ziyadee Hospital
in Ardakan, and Shahid Rahnemoon Hospital in Ya

Full name of responsible person

Somayeh Azimpour

Street address

Ardakan, Meybod, Yazd Hospital

City

Ardakan, Meybod, Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Rafsanjan University of
Medical Sciences

Full name of responsible person

Dr Hamid Hakimi

Street address

Rafsanjan, University of Medical Sciences

City

Rafsanjan

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research, Rafsanjan 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
Rafsanjan Nursing and Midwifery College

Full name of responsible person
Somayeh Azimpour

Position
Msn in Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific 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