Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of vibration and massage on symptoms of RLS and quality of sleep in heamodialese 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 vasoskeletoneurological 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

Rafsenjan 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 heamodialese patients

Public title

The effect of vibration and massage on symptoms of RLS and quality of sleep in heamodialese 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 vascularand 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 dialysiis

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, Ziyaee 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

Street address

Kerman, Rafsanjan

City

Ardakan

Postal code

8951933861

Phone

+98 35 3222 3209

Fax

Email

Somayeh.azimpour.pn@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Habibolla Hosseini

Position

Phd In Nursing

Other areas of specialty/work

Street address

Kerman, Rafsanjan

City

Rafsanjan

Postal code

Phone

+98 913 191 7915

Fax

Email

S.hosseini@rums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Kerman, Rafsanjan

City

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Postal code

8951933861

Phone

+98 35 3222 3209

Fax

Email

somayeh.azimpour.pn@gmail.com

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