Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of light pressure stroking massage with olive oil and placebo on severity of restless legs syndrome in patients undergoing hemodialysis

Protocol summary

Study aim

Comparison of the effect of light pressure stroking massage with olive oil and placebo on severity of restless legs syndrome in patients undergoing hemodialysis

Design

In this research, 60 eligible patients referring to hemodialysis department of Qom Kamkar Arab Nia hospital were chosen. Then, patients were randomly divided into two control and intervention groups.Patients will be allocated to two equal groups of massage with olive oil and placebo using blocking randomization method.

Settings and conduct

This study will be conducted on hemodialysis department of Qom Kamkar Arab Nia hospital.Patients, assessor, and also analyzer will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having chronic renal insufficiency; having restless legs syndrome; undergoing regular and consecutive hemodialysis from at least 6 months ago; doing hemodialysis at least two times weekly. Exclusion criteria: presence of open wound below the knee; having sensory and movement disorders in legs, and being unable to walking; having addiction and cigarette smoking; having anemia; having mental disorders, dementia, and mental retarders.

Intervention groups

Before the hemodialysis, both legs of patients will be irrigated and cleaned from below the knee with normal saline solution (0.9%), and then dried it with a non-sterile gaze. After one hour of hemodialysis, both legs will be messaged from below the knee to toes through light pressure stroking with olive oil or placebo. Intervention will do two times weekly until 3 weeks. International restless legs syndrome rating scale will be fulfilled in the first day and one week after the last intervention.

Main outcome variables

Severity of restless legs syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130803014251N7**
Registration date: **2017-12-13, 1396/09/22**
Registration timing: **prospective**

Last update: **2017-12-13, 1396/09/22**
Update count: **0**

Registration date

2017-12-13, 1396/09/22

Registrant information

Name

MORTEZA NASIRI

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 2622 5292

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of light pressure stroking massage with olive oil and placebo on severity of restless legs syndrome in patients undergoing hemodialysis

Public title

The effects of light pressure stroking massage with olive oil on severity of restless legs syndrome in patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range of 18-65 years old Full consciousness and being able to read and write Having chronic renal insufficiency; Having restless leg syndrome Undergoing regular and consecutive hemodialysis from at least 6 months ago Doing hemodialysis at least two times weekly

Exclusion criteria:

Having history of allergy to herbal products Presence of open wound below the knee Having sensory and movement disorders in legs, and being unable to walking Having addiction and cigarette smoking Having anemia Having mental disorders, dementia, and mental retarders

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated to groups using blocking randomization method.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients, assessor, and also analyzer will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

No, 83, No 4 Ave., Safashar Blvd

City

Qom

Province

Ghoum

Postal code

3769-87363

Approval date

2017-10-31, 1396/08/09

Ethics committee reference number

IR.MUQ.REC.1396.97

Health conditions studied

1

Description of health condition studied

Restless legs syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Severity of restless legs syndrome

Timepoint

First day of intervention and one week after the last intervention

Method of measurement

International restless legs syndrome rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After one hour of hemodialysis, both legs will be messaged from below the knee to toes through light pressure stroking with olive oil.

Category

Treatment - Other

2

Description

Control group: After one hour of hemodialysis, both legs will be messaged from below the knee to toes through light pressure stroking with placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Kamkar-Arab-Nia hospital

Full name of responsible person

Morteza Nasiri

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19 Dey St, Qom, Qom Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qom University of Medical Sciences

Full name of responsible person

Dr Hossien Saghafi

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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, Qom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Morteza Nasiri

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only a part of patients demographical data and main outcomes will be shared.

When the data will become available and for how long
Six months after data publishing

To whom data/document is available
Data will be available only for researchers working on academic and university associations

Under which criteria data/document could be used
Mention of study name Mention of authors name

From where data/document is obtainable
Morteza Nasiri: School of Paramedicine, Qom University of Medical Sciences, Qom, Iran

What processes are involved for a request to access data/document
At last one month after request

Comments