

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of the effect of Glycerine oil and Lavender oil massage on Hemodialysis patient's restless leg syndrome

Protocol summary

Summary

The purpose of this study is comparison of the effect of Glycerin oil and Lavender oil massage on Hemodialysis patient's restless leg syndrome. This study is randomized Clinical trial with control group that is done in two dialysis centers. The study population consisted of patients with chronic renal failure undergoing Hemodialysis in Hemodialysis ward of Akhavan Hospital in Kashan city and Kamkar Hospital in Qom city, Iran. Inclusion criteria: age between 18 - 65 years old; hemodialysis treatment for at least 6 months; regular dialysis at least twice a week; confirmation restless leg syndrome by standard questionnaire; Hemoglobin \geq 10 mg/dl; no history of allergies to plants; no open wound leg and foot; no addiction and drug abuse; lack of psychosis disease, dementia and mental retardation; no leg sensory and motor disorders. Exclusion criteria: allergic symptoms during the study; organ injury or accident during the study; new drug therapy with intervention in studies. Sample volume is 90 patients. Patients entered in the study randomly allocated into 3 groups consisting of 2 intervention groups and 1 control group. The study period is 3 weeks. The intervention group1 consisted of 30 patients that receive legs simple massage by Glycerin oil. It will be done twice a week for 3 weeks and each session lasts for half an hour during dialysis. The intervention group2 consisted of 30 patients that receive legs simple massage by 60-30cc Lavender oil 1.5%. It will be done twice a week for 3 weeks and each session lasts for half an hour during dialysis. The control group consisted of 30 patients that they receive routine care of dialysis. Before intervention and 3 episode post intervention with intervals of one week, severity of restless leg syndrome in the intervention groups and control group will be determined and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102214086N5**

Registration date: **2014-11-08, 1393/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-08, 1393/08/17

Registrant information

Name

Mohammad Aghajani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2001

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aghajani_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kashan University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Glycerine oil and Lavender oil massage on Hemodialysis patient's restless leg syndrome

Public title

The effect of simple massage with Lavender oil on restless leg syndrome in Hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 - 65 years old; hemodialysis treatment for at least 6 months; regular dialysis at least twice a week; confirmation restless leg syndrome by standard questionnaire; Hemoglobin \geq 10 mg/dl; no history of allergies to plants; no open wound leg and foot; no addiction and drug abuse; lack of psychosis disease, dementia and mental retardation; no leg sensory and motor disorders. Exclusion criteria: allergic symptoms during the study; organ injury or accident during the study; new drug therapy with intervention in studies.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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**

Kashan University of medical Science

Street address

Ghotbe Ravadi, Kashan

City

Kashan

Postal code**Approval date**

2014-10-07, 1393/07/15

Ethics committee reference number

93139

Health conditions studied**1****Description of health condition studied**

Restless leg syndrome

ICD-10 code

Other diso

ICD-10 code description

G99

Primary outcomes**1****Description**

Restless leg syndrome severity

Timepoint

Pre intervention and 3 episode post intervention with intervals of one week

Method of measurement

international standard restless leg syndrome questionnaire

Secondary outcomes

empty

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

The intervention group1 consisted of 30 patients that they receive legs simple massage by glycerin oil. Glycerin Oil in this group of patients is only for convenience massage. It done twice a week for 3 weeks and each session lasts for half an hour.

Category

Treatment - Drugs

2**Description**

The intervention group2 consisted of 30 patients that they receive legs simple massage by 60-30cc Lavender oil 1.5%. It done twice a week for 3 weeks and each session lasts for half an hour.

Category

Treatment - Drugs

3**Description**

The control group consisted of 30 patients that they receive routine care of dialysis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Akhavan Hospital
Full name of responsible person
Seyed Hossein Hashemy
Street address
City
Kashan

2

Recruitment center

Name of recruitment center
Kamkar Hospital
Full name of responsible person
Seyed Hossein Hashemy
Street address
City
Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research & Technology, Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
Street address
Ghotbe Ravandi, Kashan
City
Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research & Technology, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Seyed Hossein Hashemy

Position

Ms Student of Critical Nursing Care

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Master

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Full name of responsible person

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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