Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≥ 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

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Name of organization / entity
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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 syndrom by standard questionnaire; Hemoglobin ≥ 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
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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