

# 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

##### Email address

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**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Muhammad Aqhajani

**Position**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Kashan University of Medical Sciences

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Mohammad Aghajani

**Position**

Masters

**Other areas of specialty/work**

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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*