Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of the effect of massage with lavender essence and orange essence on restless legs syndrome and quality of sleep in hemodialysis patients.

Protocol summary

Summary

Objective: Comparison of the effect of foot massage with essential oil of lavander oil and orange essential oil on restless leg syndrome and sleep quality of patients undergoing hemodialysis. Design: a randomized clinical trial. Setting and conduct: Hemodialysis patients referring to Hospital Shahid beheshti and Besat in Hamadan for dialysis, are eligible for inclusion in the study. Inclusion criteria: Aged 18-65 years, have a history of at least 3 months of hemodialysis, answering "yes" to the first four questions of the restless leg syndrome questionnaire, no diabetic foot ulcers. Exclusion criteria: Failure to cooperate during study,A candidate for kidney trasplantation during the study. Intervention: 105 patients are randomly divided into 3 groups of 35 subjects after entering the study (lavender essential oil group, orange essential oil group and control group). Massage for 3 weeks and 3 times per week during hemodialysis for half an hour in the intervention group. In the control group, no massage is performed. Primary outcome: Sleepy sleep syndrome and sleep quality are measured before and after the first, second and third week, using the International Pittsburgh Sleep Disorder Syndrome Questionnaire. Secondary outcome: Nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071532303N3**
Registration date: **2017-08-31, 1396/06/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-31, 1396/06/09

Registrant information

Name
Morteza Shamsizadeh
Name of organization / entity
Hamadan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of massage with lavender essence and orange essence on restless legs syndrome and quality of sleep in hemodialysis patients.

Public title

Effect of foot massage with essential oil of lavender and essential oil of orange on restless leg syndrome and sleep quality in hemodialysis patients.

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Aged 18-65 years, have a history of at least 3 months of hemodialysis, have at least 3 sessions of hemodialysis per week, answering "yes" to the first four questions of the restless leg syndrome questionnaire, having sleep problem based on scores resulting from pittsburg questionnaire, no diabetic foot ulcers, no control of restless legs syndrome including antidepressants, no serious complications in the leg And foot ulcer and peripheral neuropathy and vascular problems in the lower limbs based on examination of the physician and the documentation in the case; Exclusion criteria: Failure to cooperate during study, A candidate for kidney trasplantation during the study, The onset of diabetic foot ulcers during the study,Discontinuation of hemodialysis sessions for any reason during the study(like traveling or kidnry transplant)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The samples were randomly assigned to three groups of 35 people (massage with essential oil of lavander, massage with orange essential oil and control group) by random blocking.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciencs
Street address
Fahmide Street, Hamadan University of Medical Sciences, Hamadan
City
Hamadan
Postal code
651783-8698
Approval date
2017-06-22, 1396/04/01
Ethics committee reference number
IR.UMSHA.REC.1396.213

Health conditions studied

1

Description of health condition studied
Hemodialysis Patients
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, Stage 5

Primary outcomes

1

Description
Restless leg syndrome
Timepoint
Before the intervention, the first week, the second and third after the intervention
Method of measurement
Restless leg Syndrome Questionnaire

2

Description
Sleep quality
Timepoint
Before intervention. First, second and third weeks after intervention
Method of measurement
Pittsburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First, a skin test was performed to ensure insensitivity and then massage with essential oil of lavender for half an hour during dialysis 3 times a week for 3 weeks totaling 9 times.
Category
Treatment - Other

2

Description
After performing the skin test and making sure that there was no sensitivity, massage was done with essential oil of orange for half an hour during hemodialysis 3 times a

week for 3 weeks and 9 times in total.

Category

Treatment - Other

3

Description

There was no action in the control group and they received routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Shahid Beheshti

Full name of responsible person

Fariba Mirzajani lotomi

Street address

Hamadan

City

Hamadan

2

Recruitment center

Name of recruitment center

Hospital Besat

Full name of responsible person

Fariba Mirzajani lotomi

Street address

Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Fariba Mirzajani Lotomi

Street address

Fahmide street, Hamadan University of Medical Sciences, Hamadan

City

Hamadan

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, Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Fariba Mirzajani Lotomi

Position

Msn in Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Khodayar Oshvandi

Position

Phd in Nursing,Faculty of Nursing and Midwifery

Other areas of specialty/work

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Person responsible for updating data

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Ms, Faculty of Nursing and Midwifery

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