

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of aromatherapy massage on severity of restless legs syndrome in hemodialysis patients

Protocol summary

Study aim

The effect of lavender aromatherapy massage on severity of restless legs syndrome in patients undergoing hemodialysis

Design

Two arm parallel group randomised trial with blinded postoperative care

Settings and conduct

Hemodialys ward in Shahid Rahnemoun Hospital in Yazd
In test group,samples underwent aromatherapy massage on the extremities for 30 minutes during the second to third hours of dialysis.Lavender oil was used by Barij Essence Pharmaceutical Company. The massage was performed over four weeks and a total of twelve days during hemodialysis. in control group, no intervention was made Sampling was performed using convenience sampling from mothers with restless legs syndrome who had the criteria to enter the study. Samples were divided into experimental and control groups based on Permuted block randomization (with four blocks).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Dialysis-requiring acute renal failure, at least 3 months of hemodialysis,Persian-speaking, having the ability to communicate verbally, having restless legs syndrome, 3 times a week dialysis, having the physical and mental ability, Having a normal neurological and vascular condition, ferritin > 100 ng/mL, transferrin saturation > 20%, no history of asthma, migraines or allergies, no musculoskeletal disorders disabling physical activity, lack of wounds and redness of the limbs, Any allergic reaction to lavender and, no diabetes. exclusion criteria :a history of cancer, lack of a healthy sense of smell, and a refusal to continue attending the study.

Intervention groups

patients suffering from restless legs syndrome underwent aromatherapy massage on the extremities for 30 minutes. No intervention was made for the control group.

Main outcome variables

severity of Restless leg syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140708018395N3**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Akram Amrollahi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

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amrollahi.akram@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2019-12-21, 1398/09/30

Scientific title

The effect of aromatherapy massage on severity of restless legs syndrome in hemodialysis patients

Public title

The effect of oil massage therapy on severity of restless legs syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

having restless legs syndrome undertaking dialysis 3 times a week Dialysis-requiring acute renal failure at least 3 months of hemodialysis being Persian-speaking having the ability to communicate verbally having the physical and mental ability Having a normal neurological and vascular condition ferritin > 100 ng/mL transferrin saturation > 20% no history of asthma, migraines or allergies no musculoskeletal disorders disabling physical activity lack of wounds and redness of the limbs Any allergic reaction to lavender and

Exclusion criteria:

suffering from cancer lack of a healthy sense of smell suffering from Diabetes refusal to continue attending the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was performed based on the judgmental sampling from patients with restless legs syndrome who had the criteria to enter the study. To unify the sample size, Samples were divided into experimental and control groups based on Permuted block randomization (with two blocks) and to conceal allocation, we used (Numbered drug containers).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

No.2 building,shahid sadoughi avenue, Bahonar square

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2014-12-07, 1393/09/16

Ethics committee reference number

187650

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

rls

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

RLs

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

the severity of restless legs syndrome

Timepoint

before the study and intervention- the last session of the study and intervention

Method of measurement

restless legs syndrome questionnaire

Secondary outcomes

empty

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

Intervention group:This study is a randomized clinical trial. The population of this study was hemodialysis patients with restless legs syndrome hospitalized in the

hemodialysis ward of Shahid Rahnemoun Hospital in Yazd. Sampling was performed by convenience method and randomly assigned into 2 groups.. The research units underwent effleurage massage on the extremities along with lavender oil for 30 minutes during the second to third hours of dialysis, 3 times a week by researchers. The amount of oil used for each massage therapy session was 10 cc, and each foot was massaged for 15 minutes. Lavender oil was used by Barij Essence Pharmaceutical Company. The massage was performed over four weeks and a total of twelve days during hemodialysis by colleagues of the same-sex patient who had been trained.

Category

Treatment - Other

2

Description

Control group: No intervention was made for the control group, and they were only asked to move their legs during hemodialysis to relieve symptoms. Samples of the control group of patients undergoing hemodialysis were selected on Saturdays, Mondays, and Wednesdays.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahneemoun Hospital

Full name of responsible person

Akram Amrollahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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Bahonar square, shahid sadoughi avenue, No.2

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Akram Amrollahi

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Akram Amrollahi

Position

Nurse

Latest degree

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