Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect Of Massage With Lavender Oil And Simple Massage On Cramping Pain Severity And Fatigue in Hemodialysis Patients In Lordegan And Borujen Cities

Protocol summary

Study aim
The Effect of lavender oil Massage and Simple Leg Muscle Massage on Crampy Pain and Fatigue During Dialysis in Hemodialysis Patients in Lordegan and Borujen

Design
This study was a cross-over clinical trial with intervention and control group.60 patients were selected using random allocation software.Samples were randomly divided into two groups of 30 each.

Settings and conduct
The research setting is the dialysis wards of Lordegan and Borujen hospitals.Prior to the intervention, the baseline assessment was performed for two weeks and during this phase, the demographic information questionnaire, the Piper Fatigue and Visual Pain Scale, fatigue severity, as well as the pain severity and frequency of cramps were recorded.

Participants/Inclusion and exclusion criteria
Entry requirements: 1. Chronic kidney failure with at least one year of hemodialysis history 2. Age range between 30 and 60 years 3. Having physical and mental ability 4. Lack of cutaneous lesions, scarring and limb redness Non-arrival conditions: 1. Catabolic diseases such as cancer 2. Diabetic neuropathy 3. Use of pain medicines, hypnotics, narcotic and psychotropic drugs 4. lower limb skeletal disorders, neuromuscular disorders and arthritis 5. Alcohol abuse 6. Allergy to lavender oil

Intervention groups
In the first group massage with olive oil and in the second group massage with lavender oil.Massage was performed for 4 weeks in all hemodialysis sessions.Each patient completed the Piper Fatigue Questionnaire and Visual Analogue Scale of Pain on the last day of dialysis each week.

Main outcome variables
Reduction of fatigue and muscle cramps during hemodialysis.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190528043741N1**
Registration date: **2019-09-18, 1398/06/27**
Registration timing: **retrospective**

Last update: **2019-09-18, 1398/06/27**
Update count: **0**

Registration date
2019-09-18, 1398/06/27

Registrant information
Name
Mohammad Alidadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-07-20, 1395/04/30
Expected recruitment end date
2016-11-19, 1395/08/29
Actual recruitment start date
2016-08-20, 1395/05/30
Actual recruitment end date
2016-12-19, 1395/09/29

Trial completion date
2017-01-02, 1395/10/13

Scientific title
The Effect Of Massage With Lavender Oil And Simple Massage On Cramping Pain Severity And Fatigue in Hemodialysis Patients In Lordegan And Borujen Cities

Public title
Effect Of Massage With Lavender Oil And Simple Massage On Cramping Pain Severity And Fatigue in Hemodialysis Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having chronic renal failure with at least one year of hemodialysis history Age range from 30 to 60 years Having physical and mental ability Loss of skin lesions, ulcers and redness of the limbs

Exclusion criteria:
Disease with catabolic processes like cancer Diabetic Neuropathy Taking medications, sleep deprivation, drugs and nerves Skin disorders of the lower limb, musculoskeletal disorders and known arthritis Lavender oil allergy

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
With the help of random allocation software, 60 patients were selected.After justifying the patients to participate in the study and obtain informed consent, the samples were randomly divided into two groups of 30.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participants in the study (patients), nurses working in the hemodialysis departments and the statistical advisor (data analyst) were kept blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yazd University of Medical Sciences

Street address
Central Building of Yazd University of Medical Sciences. Yazd, Bahonar Square,

City
Yazd

Province
Yazd

Postal code
8944158318

Approval date
2016-07-15, 1395/04/25

Ethics committee reference number
IR.SSU.MEDECINE.REC.1395.103

Health conditions studied

1

Description of health condition studied
Muscle cramps during hemodialysis

ICD-10 code
Z49.0

ICD-10 code description
Preparatory care for renal dialysis

2

Description of health condition studied
Fatigue during hemodialysis

ICD-10 code
Z49.0

ICD-10 code description
Preparatory care for renal dialysis

Primary outcomes

1

Description
Muscular cramps during hemodialysis: A score obtained from patients about the severity of pain after hemodialysis, which is measured by the visual scale of pain..

Timepoint
At the beginning of the study, 7-14-21 and 28 days after the study

Method of measurement
Visual analogue Scale Questionnaire

2

Description
Fatigue: A patient's fatigue score measured by Piper's Fatigue Questionnaire

Timepoint
At the beginning of the study, 7-14-21 and 28 days after the study
Method of measurement
Piper Fatigue Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Massage with lavender oil. Lavender oil massage was used with 10 drops of 1/5% lavender oil. Massage duration was 5 minutes and three times: one hour after dialysis, two hours after dialysis, and half an hour to the end of dialysis-Most cramps occur at this time-(15 minutes total). The massage was done in such a way that the nurse's fingers were placed around the C and the massage was performed.The back muscles were selected for massage.
Category
Treatment - Other

2

Description
Control group: Massage with olive oil.For massage, olive oil was used.Massage duration was 5 minutes and three times: one hour after dialysis, two hours after dialysis, and half an hour to the end of dialysis-Most cramps occur at this time-(15 minutes total). The massage was done in such a way that the nurse's fingers were placed around the C and the massage was performed.The back muscles were selected for massage.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Lordegan shohada Hospital
Full name of responsible person
Mohammad Alidadi
Street address
Nursing Street, Lordegan Shohada Hospital
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2

Recruitment center
Name of recruitment center
Borujen Vali Asr Hospital
Full name of responsible person
Mohammad Alidadi
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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
Street address
Bahonar Square.Central Building of Yazd University of Medical Sciences
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8916978477
Phone
+98 35 3724 0171
Email
info@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd university of medical science
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
Mohammad Alidadi

Position
Master of Critical Care Nursing

Latest degree
Master

Other areas of specialty/work
Nursery

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Nurse Street. Lordegan Shohada Hospital

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Position
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Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

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

Title and more details about the data/document
Data on major outcomes can be shared.

When the data will become available and for how long
from 2020 to 2025

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For the manufacture of drugs effective on fatigue and muscle cramps during hemodialysis

From where data/document is obtainable
Shahrekord University of Medical Sciences- Shohada Lordordan Hospital- Mr. Mohammad Alidadi. Email: Bakhtiary95@gmail.com mobile: 09132805386

What processes are involved for a request to access data/document
Sent emails will be answered within a month.

Comments