

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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)

Phone

+98 38 3444 4444

Email address

bakhtiary95@gmail.com

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

City

Lordegan

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 4444 0061

Email

Bakhtiary95@gmail.com

2

Recruitment center

Name of recruitment center

Borujen Vali Asr Hospital

Full name of responsible person

Mohammad Alidadi

Street address

Borujen, Mellat Boulevard, Shahid Banaee Blvd.

City

Borujen

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 2422 2122

Email

Bakhtiary95@gmail.com

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

City

Yazd

Province

Yazd

Postal code

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

Street address

Nurse Street. Lordegan Shohada Hospital

City

Lordegan

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8891635133

Phone

+98 38 3444 4444

Email

Bakhtiary95@gmail.com

Person responsible for scientific 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

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Other areas of specialty/work

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Email

Bakhtiary95@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Alidadi

Position

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Phone

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Email

Bakhtiary95@gmail.com

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