Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Effleurage massage With Sesame oil On Hemodialysis patient's Restless leg syndrome

Protocol summary

Summary

The aim of this study was to determine the effect of Effleurage massage with sesame oil on hemodialysis patient's restless leg syndrome.This study is a randomized clinical trial that was done on chronic renal failure patients undergoing hemodialysis that were referred to the Hemodialysis wards of ziaei Hospital of ardakan city and emam jafar sadegh Hospital in meybod city in 2016. The sampling method was convenience.60 patients that had the inclusion criteria were chosen and then were randomly allocated to two groups consisting of 30 patients. The intervention group received leg and foot Effleurage massage with sesame oil for four weeks, twice a week, and each time for 10 minutes respectively. The Control group received usual care of hemodialysis patients. One week after the end of the study, the patients completed the study tools. The results were analyzed with the, chi square and t test in SPSS version 19. Inclusion criteria:Chronic renal failure patients On Hemodialysis regularly For at Least6 months prior to Restless legs syndrome؛Regularly scheduled dialysis at least twice a week؛Ranging in age from 18 to 65 years؛Hb higher than 10 mg per deciliter Exclusion criteria:Uncooperative patient or died during the study؛Allergy symptoms during the study؛Injury or accident during study treatment؛Start a new drug treatment intervention in the study by psychiatrists؛Aggravate RLS symptoms and the lack of control؛Addiction and substance abuse, lack of disease psychosis, dementia and mental retardation؛Movement disorders in legs؛There is an open wound below the knee to the foot.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111030815N1**

Registration date: **2017-03-16, 1395/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-16, 1395/12/26

Registrant information

Name

Heydar Kalantari

Name of organization / entity

Shahid Sadoughi Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 32244658

Email address

kalantari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences Yazd

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2016-12-19, 1395/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Effleurage massage With Sesame oil On Hemodialysis patient's Restless leg syndrome

Public title

The Effect of Massage with sesame oil on Hemodialysis

patient's leg pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Chronic renal failure patients On Hemodialysis regularly For at Least6 months prior to Restless legs syndrome؛Regularly scheduled dialysis at least twice a week؛Ranging in age from 18 to 65 years؛Hb higher than 10 mg per deciliter Exclusion criteria:Uncooperative patient or died during the study؛Allergy symptoms during the study؛Injury or accident during study treatment؛Start a new drug treatment intervention in the study by psychiatrists؛Aggravate RLS symptoms and the lack of control؛Addiction and substance abuse, lack of disease psychosis, dementia and mental retardation؛Movement disorders in legs؛There is an open wound below the knee to the foot.

Age

From **77 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Shahid Sadoughi University of Medical Sciences Yazd

Street address

Yazd.Shahid Sadoughi University of Medical Sciences Yazd

City

ARDAKAN

Postal code

8944158318

Approval date

2016-02-19, 1394/11/30

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.469

Health conditions studied

1

Description of health condition studied

Hemodialysis patient's

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes

1

Description

Restless leg syndrome

Timepoint

Baseline,First week,Second week,Third week,Forth week,One week after the end of the study

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Restless legs

Timepoint

Baseline,First week,Second week,Third week,Forth week,One week after the end of the study

Method of measurement

űestionnaire

Intervention groups

1

Description

This study is a randomized clinical trial that was done on chronic renal failure patients undergoing hemodialysis that were referred to the Hemodialysis wards of ziaei Hospital of ardakan city and emam jafar sadegh Hospital in meybod city. The sampling method was convenience.60 patients that had the inclusion criteria were chosen and then were randomly allocated to two groups consisting of 30 patients. The intervention group received leg and foot Effleurage massage with sesame oil for four weeks, twice a week, and each time for 10 minutes, one hour after the start of dialysis patients, at a rate of 30 to 60 cc respectively. One week after the end of the study, the patients completed the study tools. The results were analyzed with the , chi square and t test in SPSS version 19.

Category

Other

2

Description

The Control group received usual care of hemodialysis patients.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardakan Ziaei hospital

Full name of responsible person

Mr.Dehstani

Street address

Ziaei Hospital Of Ardakan

City

Ardakan

2

Recruitment center

Name of recruitment center

Emam jafar sadegh Hospital Of Meybod

Full name of responsible person

kalantari

Street address

Emam jafar sadegh Hospital Of Meybod

City

Meybod

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd, Iran

Full name of responsible person

Dr.Ghasemi

Street address

International Campus Yazd,Iran

City

Ardakan

Grant name

0

Grant code / Reference number

0

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences Yazd, Iran

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

Shahid Sadoughi University of Medical Sciences Yazd, Iran

Full name of responsible person

kalantari Heydar

Position

Msc Student in Adult Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd, Iran

Full name of responsible person

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Position

Phd,Assisstant Professor

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Person responsible for updating data

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Full name of responsible person
Heydar Kalantari

Position
Msc Student in Adult Critical Care Nursing

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