Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Telangton's oyster massage with and without black seed oil on restless leg syndrome and the severity of muscle cramps in hemodialysis patients

Protocol summary

Study aim
Determining the effect of oyster type Telangton massage with black seed oil on restless leg syndrome and pain of muscle cramps in hemodialysis patients

Design
Randomized controlled clinical trial; with one control group, with parallel groups, single blind, phase 3 on 90 patients.

Settings and conduct
1- The place of this study is in the hemodialysis ward of Golestan Hospital in Ahvaz. 2- In this study, the research samples are not aware of the type of substance used for them during the massage.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being in the age range of 18 to 65 years; Chronic renal failure undergoing regular and continuous hemodialysis for at least 6 months; regular dialysis program at least twice a week; Having 6 muscle cramps per month, getting a score of 4 from the Restless Legs Syndrome Questionnaire. Non inclusion criteria: History of mental illness; Open sores below the knee to the sole of the foot

Intervention groups
Intervention group 1: Tillingo massage by oyster method using black seed oil twice a week for three weeks and 10 ml each time. Intervention group 2: Performing oyster massage by oyster method using paraffin oil (placebo) twice a week for three weeks and 10 ml each time. Control group: Receiving routine interventions in the ward

Main outcome variables
Restless leg syndrome score; muscle cramp induced pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160726029086N6**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date
2021-08-06, 1400/05/15

Registrant information

Name
Nasrin Elahi
Name of organization / entity
Ahvaz Jundishapur University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-26, 1400/03/05

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of Telangton's oyster massage with and without black seed oil on restless leg syndrome and the severity of muscle cramps in hemodialysis patients

Public title

The effect of Telangton massage on restless legs syndrome and pain caused by muscle cramps

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being in the age range of 18 to 65 years Chronic renal failure undergoing regular and continuous hemodialysis for at least 6 months Perform a regular dialysis program at least twice a week Having restless legs syndrome who get a score of 4 Muscle cramps according to the patient statement

Exclusion criteria:

History of mental illness Open sores below the knee to the sole of the foot

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in groups of 30 will be randomly entered into the study using the block random allocation method with blocks of size six in two intervention and the control groups based on inclusion criteria. Randomization gives each participant an equal chance of being in each group. Blocking is used to balance the number of samples assigned to each of the groups studied.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the single blind method will be used. Thus, the participants (in the intervention group) are not informed about the type of oil consumed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences and Health Services, Vice Chanc

Street address

No.7; Azerbaijan Alley; Iqbal Street; Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.AJUMS.REC.1399.892

Health conditions studied

1

Description of health condition studied

Restless legs syndrome and severe pain due to muscle cramps in patients with renal failure undergoing hemodialysis

ICD-10 code

N18.5

ICD-10 code description

نارسايي مزمن كليوي

Primary outcomes

1

Description

Change in the score of "restless legs syndrome" - the score obtained from the questionnaire is between 0 and 40, which indicates the severity of this disorder. A score of zero means that the person has no syndrome, and the higher the score, the more severe the disorder.

Timepoint

Before intervention and after intervention

Method of measurement

International Restless Legs Syndrome Questionnaire.

2

Description

Changes in pain intensity score of muscle cramps

Timepoint

Before and after intervention

Method of measurement

Use a checklist to record the severity of pain (VAS) and record the number of muscle cramps per month

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: receives oyster massage with 10 ml of black seed oil twice a week for three weeks. Massage from the soles of the feet to below the knees for 5 minutes.
Category
Treatment - Other

2

Description
Intervention group 2: receives oyster massage with 10 ml of paraffin oil (placebo) twice a week for three weeks. Massage from the soles of the feet to below the knees for 5 minutes.
Category
Placebo

3

Description
Control group: The control group will undergo routine care and treatment (such as surface massage).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hemodialysis ward of Golestan Hospital
Full name of responsible person
Parvane Asadollahi
Street address
No.7; Azerbaijan Alley; Iqbal Street; Golestan
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nasrinelahi137@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Nasrin Elahi
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No.7; Azerbaijan Alley; Iqbal Street; Golestan
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Nasrin Elahi
Position
Associate Professor
Latest degree
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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
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after making individuals unidentifiable. Also data analysis becomes available.
When the data will become available and for how long
After the end of the study
To whom data/document is available
Related professors. Relevant students. Researchers working in academic and scientific institutions
Under which criteria data/document could be used
To use the treatment process for hemodialysis patients
From where data/document is obtainable
Refer to the responsible author for permission.
What processes are involved for a request to access data/document
Request by email to the responsible author. elahi-n@ajums.ac.ir
Comments