Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology massage on incidence and severity of pain due to muscle cramp in hemodialysis patients

Protocol summary

Study aim
Determining the effect of foot reflexology massage on incidence and severity of pain due to muscle cramps in hemodialysis patients

Design
Clinical trials with control group and intervention group and randomized

Settings and conduct
After approving the research project and writing a written consent from the research vice chair and ethics committee of Islamic Azad University, Tehran Medical Branch, the researcher will go to the selected hospital and, by presenting the letter to the relevant center, will be allowed to enter the research environment, then by referring to the section Hemodialysis of Amir al-Momenin Hospital and Ayatollah Hospital of Esfahani Hospital, patients who have been admitted to the study are selected as samples.Patients' eyes in both groups will be evaluated on the intensity of pain and muscle cramps using a numerical scale of pain and a researcher-made questionnaire

Participants/Inclusion and exclusion criteria
Patients with a history of muscle cramp

Intervention groups
The intervention included reflexology massage for 3 weeks, three sessions per week for 15 minutes during hemodialysis on the intervention group. The group carries out routine care by nurses in the hemodialysis department.

Main outcome variables
muscle cramp

General information

Reason for update

Acronym
Reflexology

IRCT registration information
IRCT registration number: **IRCT20180717040503N1**
Registration date: **2018-10-17, 1397/07/25**
Registration timing: **retrospective**

Last update: **2018-10-17, 1397/07/25**
Update count: **0**

Registration date
2018-10-17, 1397/07/25

Registrant information

Name
Tahereh Ashktorab

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology massage on incidence and severity of pain due to muscle cramp in hemodialysis patients

Public title
The effect of reflexology on muscular cramp

hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People aged 18 to 60 years Only feminine History of at least 6 months of dialysis Patients with a history of muscle cramp Hemodialysis with sodium bicarbonate solution Being on a hemodialysis weekly list and doing it 3 times a week and every 3 to 4 hours of hemodialysis Do not link to the list when sampling Non-infectious diseases-Arthritis-Rheumatoid arthritis Not having open wound-burn-break-and deep-vein thrombosis Failure to use anti-cramps or dermatologists

Exclusion criteria:

Not having muscle cramps

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Coupled days are randomly assigned to one of the groups and 35 patients are placed in each of the groups and receive the intervention of the same group.

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 on Research in Islamic Azad University, faculty of Medicin

Street address

Shariati Avenue., Khaghani Avenue . Islamic Azad University of Medical Sciences, Tehran, Iran

City

Tehran

Province

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Postal code

1916893813

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.IAU..TMU.REC.1396.255

Health conditions studied

1

Description of health condition studied

Muscle cramps in patients undergoing hemodialysis

ICD-10 code

Care invol

ICD-10 code description

Z49

Primary outcomes

1

Description

Reduced Severity pain due to muscle cramp

Timepoint

Before and after the intervention

Method of measurement

Numerical scale of pain

Secondary outcomes

1

Description

Reduce the frequency of muscle cramps

Timepoint

Before and after the intervention

Method of measurement

researcher-made questionnaire

Intervention groups

1

Description

Intervention group: The intervention involves foot reflexology massage for 3 weeks,every week three sessions for 15 minutes during hemodialysis by the researcher after completing the course on the intervention group will be done .first, simple massage is given for 5 minutes to relaxing and relax the leg muscles. after relaxing reflexology massage points the research includes solar plexus , kidney, heart and brain given for 7 minutes.at the end again relaxing given for 3 minutes.

Category

Prevention

2

Description

The control group: received usual care by dialysis center staff.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir al-momenin hospital and Shahid ayatollah ashrafi esfahani
Full name of responsible person
Tahereh Ashk Torab
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research DeputyIslamic Azad University of Medical Sciences
Full name of responsible person
mozhgan ghasemi
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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
Research DeputyIslamic Azad 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
Islamic Azad University
Full name of responsible person
Ghasemi mozhgan
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Person responsible for updating data

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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