Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology on intensity fatigue and chronic musculoskeletal pain in hemodialysis patients

Protocol summary

Summary

Objectives:The aim of this study is the determination The effect of foot reflexology on intensity fatigue and chronic musculoskeletal pain in hemodialysis patients. Design of study: A randomized single blind without placebo controlled study in the Ali ebn abitaleb(s) hospital of Zahedan University of Medical Sciences. participants: All patients undergoing hemodialysis referring to the Ali ebn abitaleb(s) hospital in zahedan in 2017. Inclusion criteria: At least 18 years of age; A history of at least 6 months of dialysis; Be on the weekly dialysis list A sample of 90 patients (45 intervention and 45 control) will be selected. In both groups، Fatigue Severity Scale(FSS) and Visual Analogue Scale(VAS) Questionnaires (pretest) will be filled half an hour after starting dialysis. In intervention group، for half an hour, both feet of patients (each legs 15 min) will be massaged in reflex points on the soles of the feet. At the end of dialysis questionnaires will be filled in both groups (posttest). In intervention group massage will be done for three consecutive sessions of dialysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100736612N1**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice- Chancellor in Research Affairs Zahedan University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on intensity fatigue and chronic musculoskeletal pain in hemodialysis patients

Public title

The effect of foot reflexology on intensity fatigue and chronic musculoskeletal pain in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion:At least 18 years of age ; A history of at least 6 months of dialysis ; Be on the weekly dialysis list
Exclusion: Unwillingness to continue to participate in the scheme ; Injection blood products and Drugs such as Calcitrile and Venofer in intervention

Age

From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Khalije Fars Boulevard,Dr Hesabi Square

City
Zahedan

Postal code
98167-43463

Approval date
2017-09-24, 1396/07/02

Ethics committee reference number
IR.ZAUMS.REC.1396.155

Health conditions studied

1

Description of health condition studied
fatigue

ICD-10 code
F48.0

ICD-10 code description
Neurasthenia

2

Description of health condition studied
chronic musculoskeletal pain

ICD-10 code
R52.2

ICD-10 code description
Other chronic pain

Primary outcomes

1

Description
fatigue

Timepoint
Before and immediately after the intervention

Method of measurement
Fatigue Severity Scale

2

Description
Chronic musculoskeletal pain

Timepoint
Before and immediately after the intervention

Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group، for half an hour, both feet of patients (each of the legs 15 min) reflex points on the soles of the feet massage will be given.(Massage on the foot of the foot will apply at the point that is related to the kidneys)

Category
Other

2

Description
in control group no intervention required

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali ebn abitaleb(s) hospital

Full name of responsible person
Abouzar shamsoddini

Street address
Zahedan University of Medical Sciences

City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice- Chancellor in Research Affairs Zahedan University of Medical Sciences
Full name of responsible person
Dr noormuhammad bakhshani
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Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice- Chancellor in Research Affairs Zahedan University of Medical Sciences
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

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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*