Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of foot reflexology massage on pain intensity during vascular needle insertion in hemodialysis patients

Protocol summary

Study aim
The effect of foot reflexology massage on pain intensity during vascular needle insertion in hemodialysis patients

Design
Clinical trial with parallel control group, double blind, randomized, single center trial, Sample size 30 people.

Settings and conduct
Shahid Beheshti Hospital, Babol According to the protocol, reflexology massage is performed in three weeks (once a week) for 5 minutes on the sole of the left foot in the area of the solar plexus. After the intervention, the arterial needle is inserted into the vessels near the fistula site and after one minute after being fixed, the pain intensity is measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 years and above; Minimum literacy to recognize numbers; Performing hemodialysis through an arteriovenous fistula in the left hand; At least two months have passed since the start of hemodialysis through the fistula; Absence of simultaneous pain in other parts of the body; Male gender. Exclusion Criteria: Intolerance of pressure and massage in the area of the sole of the left foot; The presence of injury or lesion in the massage place; Death and travel.

Intervention groups
Intervention group 1: In this group, according to the protocol, reflexology massage is performed in three weeks (once a week) for 5 minutes on the sole of the left foot in the area of the solar plexus. After the intervention, the arterial needle is inserted into the vessels near the fistula site and after one minute after being fixed, the pain intensity is measured. Intervention group 2: In this group, according to the protocol, massage is performed for 5 minutes at the opposite point of the solar plexus area on the back of the foot. Control group: No treatment is done and only routine treatment is done. It is only for comparison with the intervention group.

Main outcome variables
Pain intensity.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N74**
Registration date: **2022-12-24, 1401/10/03**
Registration timing: **prospective**

Last update: **2022-12-24, 1401/10/03**
Update count: **0**

Registration date
2022-12-24, 1401/10/03

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-31, 1401/10/10

Expected recruitment end date
2023-03-30, 1402/01/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology massage on pain intensity during vascular needle insertion in hemodialysis patients

Public title
The effect of foot reflexology massage on pain intensity during vascular needle insertion in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years and above Minimum literacy to recognize numbers Performing hemodialysis through an arteriovenous fistula in the left hand At least two months have passed since the start of hemodialysis through the fistula. Absence of simultaneous pain in other parts of the body Male gender

Exclusion criteria:
Intolerance of pressure and massage in the area of the sole of the left foot The presence of injury or lesion in the massage place Death and travel

Age
From **18 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 4). Using Sealed Envelope software to generate random number tables.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Outcome assessor and analyzer and participant will be blind (double blind) and will not be aware from grouping. Definition of groups A, B and C will be available to analyzer and outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2022-10-10, 1401/07/18

Ethics committee reference number
IR.SEMUMS.REC.1401.166

Health conditions studied

1

Description of health condition studied
Intensity of pain

ICD-10 code
G89

ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Pain intensity

Timepoint
Before and after the intervention

Method of measurement
Numeric Pain Rating Scale (NRPS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, according to the protocol, reflexology massage is performed in three weeks (once a week) for 5 minutes on the sole of the left foot in the area of the solar plexus. After the intervention, the arterial needle is inserted into the vessels near the fistula site and after one minute after being fixed, the pain intensity is measured.

Category
Treatment - Other

2

Description
Intervention group 2: In this group, according to the protocol, massage is performed for 5 minutes at the opposite point of the solar plexus area on the back of the foot.
Category
Treatment - Other

3

Description
Control group: No treatment is done and only routine treatment is done. It is only for comparison with the intervention group.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Mohammadreza Asgari
Street address
Babol, Shahid Ghasemi St
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4716681451
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Fatemeh Ehsani
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fatemehehsani59@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Mohammadreza Asgari
Position
Associate professor
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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available