

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

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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Mazandaran

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4716681451

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are20935@gmail.com

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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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

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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