Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

The effect of foot reflexology on pain intensity associated with needle insertion into arteriovenous fistula in hemodialysis patients: a parallel randomized clinical trial study

Protocol summary

Study aim
Determining the effect of foot reflexology on pain intensity associated with insertion of a needle into an AVF in hemodialysis patients

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, on 60 patients. For randomization, a computer random number table with blocks of four and six with a ratio of 1:1 was used.

Settings and conduct
Female patients with AVF referred to Imam Reza Hospital in Tabriz will be selected by available methods and after reviewing the basic characteristics of patients will be randomly divided into two groups. In the intervention phase, each group will be evaluated for three sessions. In the intervention group, first the physiological parameters of the patients will be evaluated and then the foot reflexology will be performed for 20 minutes. After that, a needle is inserted and Information will be recorded. In the control group, information is recorded without intervention. Blinding will be done with the help of a researcher who is not familiar with the goals of the project.

Participants/Inclusion and exclusion criteria
Inc: 1. Being 18 years old and older 2. Having full consciousness 3. History of hemodialysis for at least 3 months from the desired fistula Exc: 1. Candidate for kidney transplant 2. Death of the patient or withdrawal from the study 3. Get painkillers 12-8 before hemodialysis 4. Drug addiction 5. Neuropathological problems of skin diseases in the patient's legs 6. Any type of wound and fracture, amputation and deep vein thrombosis in the legs

Intervention groups
In the intervention group, during three sessions, first the physiological parameters of the patients are evaluated and then the reflexology of the foot will be performed for 20 minutes. Are recorded without intervention.

Main outcome variables
The effectiveness of reflexology on reducing pain when a needle is inserted into a fistula

General information

Reason for update
Some final changes were omitted.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048518N1**
Registration date: **2020-11-25, 1399/09/05**
Registration timing: **prospective**

Last update: **2020-11-26, 1399/09/06**
Update count: **1**

Registration date
2020-11-25, 1399/09/05

Registrant information

Name
seyedeh faezeh razavi ghazani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3332 2334

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-05, 1399/09/15

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of foot reflexology on pain intensity associated with needle insertion into arteriovenous fistula in hemodialysis patients: a parallel randomized clinical trial study

Public title
The effect of foot reflexology on pain intensity associated with fistula needle insertion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being 18 years old and older Having full consciousness History of hemodialysis for at least 3 months from the desired fistula
Exclusion criteria:
Candidate for kidney transplant Patient death or withdrawal Get painkillers 12-8 before hemodialysis Drug addictions Neuropathological problems of skin diseases in the patient's legs Any type of wound and fracture, amputation and deep vein thrombosis in the leg
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients who will enter the study will be randomly assigned to two groups (reflexology recipient and one group receiving routine care) in a ratio of 1: 1 using a computer random number table with blocks of four and six. Blocking will be done by a non-involved person in sampling who is not aware of the objectives of the study, and the type of intervention received will be written on paper and numbered in a series of opaque envelopes (Allocation Concealment).
Blinding (investigator's opinion)
Single blinded
Blinding description
The assistance of a researcher who registers the parameters and is unaware of the allocation groups will be considered a blind member.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences - School of Nursing and Midwifery
Street address
Tabriz - University Street - Research Deputy
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Approval date
2020-11-25, 1399/09/05
Ethics committee reference number
IR.TBZMED.REC.1399.809

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
Z49.01
ICD-10 code description
Encounter for fitting and adjustment of extracorporeal dialysis catheter

Primary outcomes

1

Description
pain
Timepoint
When inserting a needle into a venous artery fistula
Method of measurement
Pain intensity in patients with arteriovenous fistula using the VAS instrument, which is a rule-like diagram numbered from zero to ten; Will be evaluated. The Linear-Visual Pain Scale is divided from zero to ten so that zero means painless and ten means maximum pain.

2

Description
Physiological parameters
Timepoint
Before and immediately after insertion of the needle into the venous artery fistula
Method of measurement

Blood pressure and heart rate with a physiological device for measuring digital blood pressure and blood oxygen saturation level by a device for measuring blood oxygen saturation level

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the necessary coordination with the center and due to the current situation in the medical centers, after wearing personal protective equipment, the researcher and the research assistant will be present at the patient's bedside. After the patient enters the ward and is placed in a dialysis bed that has a well-lit and well-ventilated environment and is quiet, the intervention will begin after the necessary coordination with the head of the ward. After ensuring that the patient's legs are clean in a comfortable, semi-sitting position with the head at a 30-degree angle to the body and a small pillow under the legs for comfort, the fistula needle is placed by each patient's fixed nurse in shifts. Morning and evening work will be done in the dialysis ward of Imam Reza (AS) Hospital in Tabriz. In each session, only two patients will be evaluated. Five minutes after cleaning the skin surface with a 70% alcohol-soaked cotton swab, a hemodialysis needle will be inserted into the fistula area by each patient's fixed nurse. In all cases, the fistula needle is the same in terms of size (No. 16), shape and manufacturer and will enter the patient fistula at an angle of 20-30 degrees. The duration of each reflexology session will be 20 minutes starting from the right foot and continuing with the left foot (10 minutes reflexology for the right foot and 10 minutes reflexology for the left foot). Massage all parts of the right foot for 5 minutes, then massage for 5 minutes on the kidneys, under the big toe and the star network (solar plexus), then repeat these steps for the left foot. Foot reflexology by researchers After washing the hands, according to the patient's preference, his feet will be cleaned with water or a wet handkerchief. To prevent friction, turquoise baby oil made in Iran at room temperature, which has no therapeutic properties, will be used. During the intervention, the researcher will support the patient's foot with one hand and massage with the fingers of the other hand (mostly the big toe) with a gentle pressure as far as the patient can bear. In the reflexology group, patients with arteriovenous fistulas will be evaluated and recorded by a researcher after completing a 20-minute foot massage and immediately after the fistula needle is inserted. Physiological parameters are evaluated by the researcher before the intervention and then reflexology is performed for twenty minutes. After reflexology is completed, the fistula needle is inserted into the fistula by the ward nurse, after which the physiological parameters of the patients will be evaluated and recorded again by the researcher.

Category

Other

2

Description

Control group: They will receive routine care, assessment of pain intensity and physiological parameters will be performed simultaneously with the reflexology group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital, Tabriz

Full name of responsible person
Seyedeh Faezeh Razavi Ghazani M.Sc. Student of Internal Medicine-Surgery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Alehe Seyyedrasouli

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Seyedeh Faezeh Razavi Ghazani

Position
Master student of Internal Surgery Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Bachelor

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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
Study data can be published after the journals are accepted and published

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
People who want to help hemodialysis patients are allowed to use the data

Under which criteria data/document could be used

People who are researcher

From where data/document is obtainable

The person in charge of the study

What processes are involved for a request to access data/document

Prove the purpose of the data request, which is to help hemodialysis patients, then send an email to the responsible author

Comments