

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of warm footbath with and without vibration on arteriovenous fistula puncture-related pain in hemodialysis patients at educational - medical hospitals of Qazvin.

Protocol summary

Summary

Objectives are: to determine the effect and compare warm footbath with and without vibration on arteriovenous fistula puncture-related pain; to determine and compare amount of fistula puncture-related pain at three methods and to determine demographic characteristics associated with fistula puncture-related pain. Design: this research is an experimental study of the clinical trial with pre-test - post-test method. Setting and conduct: Pain measurement of all cases has performed during the six intermittent hemodialysis sessions for each of the three methods without, primary and secondary intervention. After each of the six study sessions it is two weeks time interval. Participants including major eligibility criteria: 31 eligible patients have been selected through simple random sampling and are being in one group by the main Inclusion criteria: having an arteriovenous fistula; age between 17-65 years and the main exclusion criteria: no need to go on hemodialysis. Intervention: In both methods of intervention samples in the supine position with bending the knees are submerged legs above the ankle in the 40 ± 2 ° C water for ten minutes. Embedding fistula needles is done ten minutes after the start of the intervention and immediately after that, the patient is asking to determine the number of pain intensity on pain ruler. Main outcome variables: pain intensity, footbath with vibration method; footbath without vibration method

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091114634N1**
Registration date: **2013-12-09, 1392/09/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-09, 1392/09/18

Registrant information

Name

Zahra Abbas Ali Madadi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of warm footbath with and without vibration on arteriovenous fistula puncture-related pain in hemodialysis patients at educational - medical hospitals of Qazvin.

Public title

Effect of warm footbath on arteriovenous fistula puncture-related pain in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Major inclusion criteria: having an arteriovenous fistula; absence of evidence of peripheral vascular disease; no wounds to both legs above the ankle area; there is no impairment of consciousness and knowledge of the time and place and person; the ability to communicate verbally and audio; having age between 17-65 years; the last three months of fistula placement; no history of diabetes; no history of sensory and neurological disorders; Lack of consistent use of the substance, drug or relieve method to be effective on pain of fistula Needles. Major exclusion criteria: No need to go on hemodialysis; patients travel long; kidney transplantation; lack of consent to continue to participate in the study; the patient dies; if the patient is reported any other pain at evaluation or intervention time and or used of the substance, drug or relieve method which be effective on pain of Fistula Needles, excluded from the dialysis session and the next session will be enrolled in the study again but if this process is repeated in several sessions the patient will be completely excluded.

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid

Bahonar Boulevard, Qazvin

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Qazvin

Postal code

3419759811

Approval date

2013-07-10, 1392/04/19

Ethics committee reference number

7652/20/28

Health conditions studied**1****Description of health condition studied**

Arteriovenous fistula puncture-related pain in hemodialysis patients

ICD-10 code

T82.4

ICD-10 code description

Mechanical complication of vascular dialysis catheter

Primary outcomes**1****Description**

Pain intensity

Timepoint

In every hemodialysis session

Method of measurement

By using a numerical pain intensity scale (pain ruler)

2**Description**

Footbath with vibration method

Timepoint

Six intermittent hemodialysis sessions

Method of measurement

Method mentions in the information form

3**Description**

Footbath without vibration method

Timepoint

Six intermittent hemodialysis sessions

Method of measurement

Method mentions in the information form

4**Description**

Age

Timepoint

First meeting of evaluation

Method of measurement

Based on year in the information form

5

Description

Sex

Timepoint

First meeting of evaluation

Method of measurement

Based on sex in the information form

6

Description

Hemodialysis times a week

Timepoint

First meeting of evaluation

Method of measurement

Times number mentions in the information form

7

Description

The duration of arteriovenous fistula

Timepoint

First meeting of evaluation

Method of measurement

Based on year and month in the information form

8

Description

Arteriovenous fistula site

Timepoint

First meeting of evaluation

Method of measurement

Site mentions in the information form

9

Description

History of previous AVF

Timepoint

First meeting of evaluation

Method of measurement

Yes or no mentions in the information form

Secondary outcomes

empty

Intervention groups

1

Description

This research will be an experimental study of the clinical trial with pre-test - post-test method with one group. After learning how to use a pain ruler to Samples, pain assessment will be performed by it. At first pain intensity measurement of all cases will be performed during the six intermittent hemodialysis sessions without intervention then it will be two weeks time interval. In the next step during the six intermittent hemodialysis sessions warm footbath with vibration done and the pain

will be assessed after the intervention then it will be two weeks time interval again. In the final step during the six intermittent hemodialysis sessions warm footbath without vibration done and the pain will be assessed after the intervention. In both methods of intervention samples in the supine position with bending the knees will submerge their legs into the warm water. Legs will be submerged above the ankle in the 40 ± 2 ° C water for ten minutes. Embedding fistula needles will be ten minutes after the start of the intervention and immediately after that, the patient will be asked to determine the number of pain intensity on pain ruler. After the intervention, the patient's feet will be dry with a disposable towel. In the first method warm footbath with vibration will be done by using footbath massager machine made in Germany. The device is adjustable and constant water temperature of 40 ± 2 ° C is the same as it is able to induce vibrations in the water. It should be noted that the device is not for personal use and it is washable and disinfection after each use, which will be done after each intervention. In the second method warm footbath without vibration will be done by using a plastic pan and pouring the 40 ± 2 ° C water inside it. Initially as a pilot the 40 ± 2 ° C water will be poured into plastic pan and its temperature will be measured continuously for ten minutes until the water temperature drops be determined then by removing amounts of water from the pan and adding the same amount of warm water, amount of water that must be added and removed during the study and the time required will be determined as the temperature of the water in the plastic pan is kept constant at 40 ± 2 ° C. For all samples, the same size and shape of the plastic pans will be used. Plastic pan also will be washed and disinfected after each intervention. Water temperature will be measured by a standard mercury thermometer.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis center of educational - medical hospitals of Qazvin

Full name of responsible person

Zahra Abbas Ali Madadi master student of intensive care nursing

Street address

North Ferdoosi avenue, above the Mehregan hospital, dialysis center of educational - medical hospitals of Qazvin, Qazvin

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Zeinab Jourabchi

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Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

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Grant name

د/8/پ

Grant code / Reference number

28/6/8498

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Qazvin 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**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Abbas Ali Madadi

Position

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Jalil Azzimian

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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