Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
City
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
Qazvin

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
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Zahra Abbas Ali Madadi
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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