Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of cryotherapy and acupressure on pain intensity of arteriovenous fistula cannulation in female patients undergoing hemodialysis

Protocol summary

Study aim

Comparing the effect of cryotherapy and acupressure on pain intensity of arteriovenous fistula in female patients undergoing hemodialysis

Design

In this study, 42 female patients under hemodialysis were selected through fistula and entered the study, and the study is a one-way semi-experimental study in which each individual has control. for each patient, randomized intervention (cryotherapy or acupuncture)selected.

Settings and conduct

The researcher referred to hemodialysis ward in even and odd days and in the morning and evening, and selected eligible individuals based on non-random allocation No intervention: Arterio-venous hemodialysis needles were inserted by the nurse to the fistula. After completing the work and fixing the needles, pain was measured using a numerical tool. Patients were randomly assigned to cryotherapy or acupressure in the second session of hemodialysis. and third session received crayotherapy or acupressure (that did not receive in the second session) Cryotherapy intervention:It was done using a piece of cubic ice was placed inside a gauze and then inserted into the nylon and placed on the Hugo point in the patient's hand no fistula for 10 minutes (2 minutes rubbing and 15 seconds rest). Immediately after that ,the nurse inserted needle into the fistula and fixed ,the pain was measured. Acupressure intervention: It was done using a thumb-fist, the hand is oblique on the Hugo's point in the patient's hand no fistula for 10 minutes, alternately (2 minutes massage ,medium pressure, and 15 seconds rest), . Immediately after that ,the nurse inserted needle into the fistula and fixed ,the pain was measured. The instrument was used to measure the time of the hour and the pain was measured by an individual who was not aware of the type of intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria include: aged over 18 years, alertness, ability to communicate verbally, pass 3 months of fistula placement, no opioid, sleep pill or sedative from 8 hours before hemodialysis, no severe pain in other places, no Pacemaker, initiation of hemodialysis at least 3 months ago, patients with a fixed and active file (3 sessions every week each session 4 hours), no problem, lack of numbness, no neuropathy and peripheral vascular diseases around hemodialysis site (at the site of access to the vessels), no history of diabetes (or controlled if patient has diabetes). Exclusion criteria: dissatisfaction for participating in study.

Intervention groups

In this study, three stages (without intervention-intervention of cryotherapy and acupressure intervention) were performed in one group. Indeed, each individual had a control (herself) and we did not have separate control group.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180101038178N1**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **retrospective**

Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Fatemeh Hosseinzadeh

Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-02-16, 1395/11/28
Expected recruitment end date
2017-05-18, 1396/02/28
Actual recruitment start date
2017-02-16, 1395/11/28
Actual recruitment end date
2017-05-18, 1396/02/28
Trial completion date
empty

Scientific title
Comparing the effect of cryotherapy and acupressure on pain intensity of arteriovenous fistula cannulation in female patients undergoing hemodialysis

Public title
Comparing the effect of cryotherapy and acupressure on pain intensity of arteriovenous fistula cannulation in female patients undergoing hemodialysis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Being alert The ability to communicate verbally The fistula is inserted three months ago No receive a medication for sedation from 8 hours before hemodialysis Lack of severe pain in other part of body No pacemaker Initiating hemodialysis at least 3 months ago Patients with a fixed and active file to undergo hemodialysis (three sessions in a week, 4 hours each session) No skin problem, No neuropathy, No peripheral vascular diseases in the area of access to vessels
Exclusion criteria:
Dissatisfaction to participate in the study
Age
From **46 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **42**
Actual sample size reached: **42**
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 Shahed University
Street address
Intersection of Valiasr and Taleghani streets؛Faculty of Nursing and Midwifery
City
Tehran
Province
Tehran
Postal code
۳۳۱۹۱۱۸۶۵۱
Approval date
2017-02-02, 1395/11/14
Ethics committee reference number
IR.Shahed.REC.1395.199

Health conditions studied

1

Description of health condition studied
Hemodialysis, Arteriovenous Fistula, Pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Three days - every other day
Method of measurement
Numeric pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: No intervention- The first stage of the study without any intervention after the needle was inserted into the fistula, the patient's pain was measured using a numerical instrument of pain.

Category

Prevention

2

Description

Cryotherapy intervention: The researcher put a piece of ice inside a gauze (because the ice melts in the gauze later), and then placed inside the nylon and set on the Hugo point (between thumb and pointing finger) in thepatient's hand no fistula and rubbed the place from the 10 minutes (2 minutes rubbing and 15 seconds rest) before the needle was inserted into the arteriovenous fistula. Then the fistula area was well disinfected and the needle inserted into the fistula by the nurse. Immediately after insertion of the needle and fixing it, the patients' pain was measured using a numerical instrument of pain by an individual who was not aware of the type of intervention

Category

Prevention

3

Description

Acupressure intervention: The researcher carried out using the thumb of the hand in a diagonal direction on the Hugo point (between thumb and pointing finger in the patient's hand no fistula) 10 minutes before insertion of the needle, alternately (2 minutes massage, medium pressure (not too intense or very mild), and 15 seconds rest). Then , the nurse inserted needles into the fistula and fixed it, after that the number of pain was measured by a person who was not aware of the type of intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa kerman Hospital

Full name of responsible person

Abbas Pardakhty

Street address

Shafa Hospital, Kerman; North Farabi Street

City

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Province

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7618751151

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abpardakhty@kmu.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Specialized clinic of Javad Alamem Kerman

Full name of responsible person

Mohammad Hossein Pour Ebrahimi

Street address

Specialized clinic of Javad Alamem Kerman؛Alley 25-North Abu Dhar St.

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f.hosseinzadeh@ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kaysalari

Street address

University of Shahed; Persian Gulf highway opposite Imam Khomeini's shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 3092

Email

kiasalari@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Fatemeh Hosseinzadeh

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nasrin Alaee

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Fatemeh Hosseinzadeh

Position

Nurse

Latest degree

Master

Other areas of specialty/work

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Email

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available