

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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 cryotherapy 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	Not blinded
Iran (Islamic Republic of)	Blinding description
Phone	Placebo
+98 34 3342 3902	Not used
Email address	Assignment
f.hosseinzadeh@shahed.ac.ir	Single
	Other design features
Recruitment status	
Recruitment complete	
Funding source	Secondary ids
	empty
Expected recruitment start date	Ethics committees
2017-02-16, 1395/11/28	1
Expected recruitment end date	Ethics committee
2017-05-18, 1396/02/28	Name of ethics committee
Actual recruitment start date	Ethics Committee of Shahed University
2017-02-16, 1395/11/28	Street address
Actual recruitment end date	Intersection of Valiasr and Taleghani streets:Faculty of Nursing and Midwifery
2017-05-18, 1396/02/28	City
Trial completion date	Tehran
empty	Province
	Tehran
Scientific title	Postal code
Comparing the effect of cryotherapy and acupressure on pain intensity of arteriovenous fistula cannulation in female patients undergoing hemodialysis	۳۳۱۹۱۱۸۶۵۱
Public title	Approval date
Comparing the effect of cryotherapy and acupressure on pain intensity of arteriovenous fistula cannulation in female patients undergoing hemodialysis	2017-02-02, 1395/11/14
Purpose	Ethics committee reference number
Supportive	IR.Shahed.REC.1395.199
Inclusion/Exclusion criteria	
Inclusion criteria:	Health conditions studied
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	1
Exclusion criteria:	Description of health condition studied
Dissatisfaction to participate in the study	Hemodialysis, Arteriovenous Fistula, Pain
Age	ICD-10 code
From 46 years old to 75 years old	ICD-10 code description
Gender	
Female	Primary outcomes
Phase	1
N/A	Description
Groups that have been masked	Pain
No information	Timepoint
Sample size	Three days - every other day
Target sample size: 42	Method of measurement
Actual sample size reached: 42	Numeric pain rating scale
Randomization (investigator's opinion)	
N/A	Secondary outcomes
Randomization description	empty
Blinding (investigator's opinion)	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 the patient'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

Kerman

Province

Kerman

Postal code

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Email

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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Province

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Nasrin Alaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Fatemeh Hosseinzadeh

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Latest degree

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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