

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The comparative effect of acupressure and cryotherapy on the pain of the injection in the arteriovenous fistula in the patients under hemodialysis referred to the clinical centers of Kerman University of Medical Sciences, in 2019

Protocol summary

Study aim

Determining the effect of acupressure and cryotherapy on the pain of the injection in the arteriovenous fistula in the patients under hemodialysis referred to the clinical centers of Kerman University of Medical Sciences, in 2019

Design

A crossover randomized Clinical trial with two intervention groups without blinding. Samples will be randomly assigned into two blocks of 25 samples, 25 samples in acupressure/cryotherapy group and 25 samples in cryotherapy/acupressure group by Permuted Block Randomization.

Settings and conduct

All patients undergoing hemodialysis referring to health centers of Kerman University of Medical Sciences in 1398 will form the study population. Medical centers affiliated to Kerman University of Medical Sciences will be the research environment. In this study, all of the samples will have an acupressure session and a cryotherapy session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; Being conscious; the ability of verbal communication; 3 months passed the time of fistula embedding; At least 6 months passed the time of hemodialysis Initiation; Having an active medical document; In case of diabetes, controlled diabetes. Exclusion criteria: Receiving a sedative or opiate drug for 8 hours before hemodialysis; Excessive pain in other body parts; The presence of skin problem, insensibility, neuropathic disorders and peripheral vascular disease at the site of access to the vessels.

Intervention groups

Cryotherapy/Acupressure intervention group: Session 1: Routine care. Session 2: Cryotherapy will take place. Session 3: Acupressure will take place.

Acupressure/Cryotherapy intervention group: Session 1: Routine care. Session 2: Acupressure will take place. Session 3: Cryotherapy will take place.

Main outcome variables

Pain score in numerical visual analogue pain scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170116031972N7**

Registration date: **2019-07-10, 1398/04/19**

Registration timing: **prospective**

Last update: **2019-07-10, 1398/04/19**

Update count: **0**

Registration date

2019-07-10, 1398/04/19

Registrant information

Name

Mahlagha Dehghan Anari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01
Expected recruitment end date
 2019-08-22, 1398/05/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The comparative effect of acupressure and cryotherapy on the pain of the injection in the arteriovenous fistula in the patients under hemodialysis referred to the clinical centers of Kerman University of Medical Sciences, in 2019

Public title
 The effect of accupressure and cryotherapy on the pain of the injection in the arteriovenous fistula in the patients under hemodialysis

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Being conscious Having the ability of verbal communication 3 months passed the time of fistula embedding At least 6 months passed the time of hemodialysis Initiation Having an active medical document (Weekly three sessions and each session for 3 to 4 hours of hemodialysis) In case of diabetes, their diabetes has been controlled (FBS range from 70 to 150 mg/dl and BS in the range of 120 to 250 mg/dl)
Exclusion criteria:
 Receiving a sedative or opiate drug for 8 hours before hemodialysis Excessive pain in other body parts The presence of skin problem, insensibility, neuropathic disorders and peripheral vascular disease at the site of access to the vessels

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 samples will be randomly assigned into two blocks of 25 samples, 25 samples in acupressure/cryotherapy group and 25 samples in cryotherapy/acupressure group by Permuted Block Randomization.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment

Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ebnesina St, Jihad Blvd, Somaye Crossroad, Kerman

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

IR.KMU.REC.1398.167

Health conditions studied

1

Description of health condition studied

acute postprocedural pain of needle entry into the arteriovenous fistula

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

pain score in numerical visual analogue pain scale

Timepoint

Session 1: Patient's pain will be measured under normal care conditions and after entering and fixing hemodialysis arterial-venous needles. Session 2: Patient's pain will be measured after cryotherapy and entering and fixing hemodialysis arterial-venous needles. Session 3: Patient's pain will be measured after acupressure and entering and fixing hemodialysis arterial-venous needles.

Method of measurement

The numerical visual analogue pain scale

Secondary outcomes

empty

Intervention groups

1

Description

Cryotherapy/Acupressure intervention group: Session 1: routine care and no intervention will take place. Session 2: Cryotherapy will take place, as the researcher will put a cube-shaped piece of ice inside a gauze bandage, and then place it inside a plastic bag. The researcher will place the ice cube between the thumb and the index finger on the opposite hand with no fistula. After 10 minutes (2 minutes compressive massage and 15 seconds rest periodically), before the needle is inserted into the arterial-venous fistula, The researcher will rub the Hugo point (between the thumb and the index finger in the opposite hand) with average pressure. Session 3: Acupressure will take place. The researcher, using a hand thumb, will diagonally rub the Hugo point (between the thumb and the index finger in the opposite hand) with average pressure for 10 minutes for periods of 2 minutes compressive massage and 15 seconds rest before the needle is inserted.

Category

Other

2

Description

Acupressure/Cryotherapy intervention group: Session 1: routine care and no intervention will take place. Session 2: Acupressure will take place. The researcher, using a hand thumb, will diagonally rub the Hugo point (between the thumb and the index finger in the opposite hand) with average pressure for 10 minutes for periods of 2 minutes compressive massage and 15 seconds rest before the needle is inserted. Session 3: Cryotherapy will take place, as the researcher will put a cube-shaped piece of ice inside a gauze bandage, and then place it inside a plastic bag. The researcher will place the ice cube between the thumb and the index finger on the opposite hand with no fistula. After 10 minutes (2 minutes compressive massage and 15 seconds rest periodically), before the needle is inserted into the arterial-venous fistula, The researcher will rub the Hugo point (between the thumb and the index finger in the opposite hand) with average pressure.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers affiliated to Kerman University of Medical Sciences

Full name of responsible person

Mahmood Nekoeimoghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Seyed Javad Hosseini

Position

Student of M.Sc. in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Mahlagha Dehghan

Position

Faculty member of Kerman University of Medical
Sciences

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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