Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 34 3132 5201

Email address
m_dehghan@kmu.ac.ir

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, Jahad 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
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
mahmood.nekoeimoghadam@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Ebnesina St, Jahad Blvd, Somaye Crossroad, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3226 3855
Email
vcr@kmu.ac.ir
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

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3342 7901

Email
hosseini4173@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mahlagha Dehghan

Position
Faculty member of Kerman University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5856

Email
m_dehghan86@yahoo.com

Person responsible for updating data

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

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3342 7901

Email
hosseini4173@yahoo.com

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