Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison of Thermotherapy and Cryotherapy on Pain caused with Arteriovenous Fistula Cannulation in Hemodialysis Patients in Kerman

Protocol summary

Study aim

Comparison of Thermotherapy and Cryotherapy on Pain Associated with Arteriovenous Fistula Cannulation in Hemodialysis Patients in Kerman in 2025

Design

An intervention study of the clinical trial type in parallel, prospective, and single-blind design with randomly permuted blocks of size six and a sample size of 96 patients will be designed. The randomization list is based on the Sealed Envelope Ltd. online system 2024. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 13 May 2025]. Created.

Settings and conduct

The study population will consist of all eligible patients with end-stage chronic kidney disease who attend dialysis centers affiliated with Kerman University of Medical Sciences in 2025

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 or older, at least two hemodialysis sessions in a week, at least three months of arteriovenous fistula patency with intact skin. Exclusion criteria: failing the fistula's first cannulation attempt and using anesthetic agents or medications in the fistula region within the previous 24 hours.

Intervention groups

Control Group: In the control group, cannulation will be performed by the usual method and patients in this group will receive standard care. One minute after cannulation is performed by a skilled nurse, pain intensity will be measured using the NRS scale. Warm therapy intervention group: After confirming that the temperature of the warm compress reaches 40 degrees Celsius with the infrared device (Imperial Digital Thermometer CK-T 1502), the intervention will be applied precisely at the fistula site for ten minutes. Cold therapy intervention group: A cold compress will be applied precisely at the fistula site for ten minutes.

Main outcome variables

Pain improvement due to fistula cannulation in patients on hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251001067441N1**
Registration date: **2025-10-09, 1404/07/17**
Registration timing: **prospective**

Last update: **2025-10-09, 1404/07/17**
Update count: **0**

Registration date

2025-10-09, 1404/07/17

Registrant information

Name

Zahra Isari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3281 2209

Email address

isarizahra2588@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-22, 1404/07/30

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Thermotherapy and Cryotherapy on Pain caused with Arteriovenous Fistula Cannulation in Hemodialysis Patients in Kerman

Public title
Comparison of Thermotherapy and Cryotherapy on Pain caused with Arteriovenous Fistula Cannulation

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
18 years old or older Fully aware of location, time, and person Having intact senses and the ability to speak Undergoing hemodialysis program at least twice a week Having an arteriovenous fistula for at least three months Healthy skin around the arteriovenous fistula area

Exclusion criteria:
Unsuccessful first attempt at cannulation of the fistula Use of anesthetic substances or medications in the fistula area in the past 24 hours Decrease in level of consciousness or patient death

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Taking into account the probability of dropout, the final sample size was determined as 32 participants per group. Participants will be allocated to groups in blocks of six in a randomised manner. The randomisation list was generated online using Sealed Envelope Ltd. 2024. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 13 May 2025].

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding of participants is not feasible, because, in addition to the nature of the intervention, there will be a very short interval between the application of heat therapy or cryotherapy and data collection. Nevertheless, there will be no information as to which data pertain to the intervention and control groups, though it will be recorded which data belong to each group.

Placebo
Not used

Assignment
Parallel

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
Haft Bagh Alavi highway

City
kerman

Province
Kerman

Postal code
7616913555

Approval date
2025-08-12, 1404/05/21

Ethics committee reference number
IR.KMU.REC.1404.264

Health conditions studied

1

Description of health condition studied
Patients with chronic kidney disease undergoing hemodialysis

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Pain by Numeric Rating Scale (NRS)

Timepoint
Pain intensity before the procedure and one minute after inserting the hemodialysis needle and securing the needles

Method of measurement
Numeric Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group, cannulation will be performed using the conventional method, and patients in this group will receive standard care. One minute after cannulation is performed by a skilled nurse, pain intensity will be measured using the Numeric Rating Scale (NRS).

Category

Treatment - Other

2

Description

Intervention group: Thermotherapy: A warm compress will be heated in a microwave for 2 minutes. After confirming that the temperature reaches 40°C, the intervention will be applied precisely at the fistula site for 10 minutes using infrared guidance (measured with the Imperial Digital Thermometer CK-T 1502). The application will continue up to 1 minute before cannulation. After 10 minutes, the warm compress will be removed, and the area will be disinfected with a 70% ethanol swab for 30 seconds. Cannulation will then be performed by an experienced nurse. One minute after cannulation, pain intensity will be assessed using the Numerical Rating Scale (NRS). If any adverse event occurs, the intervention will be halted and the physician will be informed.

Category

Treatment - Other

3

Description

Intervention group: Cryotherapy: A cold compress will be applied for ten minutes precisely at the fistula site. The cold compress will be placed with light pressure in an intermittent manner (fifteen seconds of application followed by a fifteen-second rest for every two minutes of cryotherapy, totaling ten minutes) and will continue up to one minute before cannulation. After ten minutes, the cold compress will be removed, and the area will be disinfected with a 70% ethanol swab for 30 seconds. Cannulation will then be performed by an experienced nurse. One minute after cannulation, pain intensity will be assessed using the Numerical Rating Scale (NRS). If any adverse event occurs, the intervention will be halted and the physician will be informed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Roya Esfandiarpour

Street address

Shafa Educational and Medical Center, Kosar Blvd

City

Kerman

Province

Kerman

Postal code

۷۶۱۸۷۵۱۱۵۱

Phone

+98 34 3121 7284

Email

shafahospital@kmu.ac.ir

2

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Nahid Hajmohammadi

Street address

Afzali Pour Educational, Medical Center, next to Shahid Bahonar University, Imam Khomeini Expressway (RA)

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5419

Email

afzalih@kmu.ac.ir

3

Recruitment center

Name of recruitment center

Javadalaeme Clinic

Full name of responsible person

Mohammad Hossein Pour Ebrahimi

Street address

Delshad Street, 25th Abdozor Street, Northern Abdozor Street

City

Kerman

Province

Kerman

Postal code

7617763811

Phone

+98 34 3253 1433

Email

r_ghazizadeh@kmu.ac.ir

4

Recruitment center

Name of recruitment center

Samin al-Hujjat (A) Charity Institute

Full name of responsible person

Ali Shamsinia

Street address

End of Shaheed Raeisi Street (formerly Rajai)

City

Kerman

Province
Kerman

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7617763811

Phone
+98 34 3271 1779

Email
info@samen-darman.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Hamid Sharifi

Street address
Semayeh Crossroads (Tahammas Abad) at the beginning of Ibn Sina Street, Research and Technology Department

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Kerman

Province
Kerman

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7613753767

Phone
+98 34 3226 3821

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
Roqayeh Mehdi Pour Raberi

Position
associated professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Beginning of Haft Bagh Olavi Expressway, Alavi campus, Razi School of Nursing and Midwifery, Iran University of Medical Sciences

City
Kerman

Province
Kerman

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Email
r_mehdipour@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Roqayeh Mehdi Pour Raberi

Position
associated professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Beginning of Haft Bagh Olavi Expressway, Alavi campus, Razi School of Nursing and Midwifery, Iran University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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Position
associated professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Beginning of Haft Bagh Olavi Expressway, Alavi

campus, Razi School of Nursing and Midwifery, Iran University of Medical Sciences

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Postal code

7616913555

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Email

r_mehdipour@kmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identification of individuals

When the data will become available and for how long

Start of the access period: 3 months after publication of results

To whom data/document is available

Data will be accessible to researchers employed at academic and scientific institutions and individuals in industry

Under which criteria data/document could be used

With authorization from the relevant bodies, non-identifiable documents will be made available to individuals. Also, the data will be usable only for scientific and research purposes or for industry.

From where data/document is obtainable

To obtain the documents, applicants can contact Zahra Isari at Kerman University of Medical Sciences, Razi School of Nursing and Midwifery, phone number 00989134400639 or email isarizahra2588@gmail.com.

What processes are involved for a request to access data/document

Applicants should submit their request by sending a letter to the specified email from the relevant organ. Researchers will respond to their email as soon as possible and no later than one week.

Comments