

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of insert a cooled needle on arteriovenous fistula puncture-related pain intensity in hemodialysis patients

Protocol summary

Study aim

pain relife in venipuncture of dialysis patients

Design

The participants Were randomly assigned to either the intervention group (N=30)or the control group (N=30)using the permuted block technique with block sizes of 6 was determined by the random selection of blocks, with the letters B and A representing the control and intervention groups, respectively.

Settings and conduct

In group A in the 1 & 2 sessions, cannulation would insert with a No.15 needle at room temperature and in 3&4 session, cannulation with needle cooled (-8 c) and the intensity of the patient's pain will be measured. In group B, in contrast to group A. Hemodialysis department Mantasariéh Hospital, Mashhad - 17Shahrivar Hospital, Mashhad

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of both arterial and venous fistula At least one month elapsed since the creation of the fistula Full consciousness and ability to articulate pain symptoms Undergoing hemodialysis three times a week Absence of dementia or Alzheimer s disease No active cancer diagnosis Proficiency in the Persian language Not currently using anesthesia Having good vision Willingness to participate in the study Ability to communicate pain experiences Stable hemodynamic status Absence of muscle and joint injuries Age 18 and above exclusion criteria: Blood pressure below 80/40 mm Hg during fistula cannulation Failure to insert the needle into the fistula on the first occasion Presence of phlebitis at the cannulation site.

Intervention groups

In the group A, in session 1, 2, after entering the needle number 15, which is at room temperature, into the artery and vein, the intensity of pain is measured separately using a 10-degree ruler. The researcher uses a cold needle for sessions 4 and 3.In group B, in contrast to group A.

Main outcome variables

The severity of pain after entering the needle for hemodialysis

General information

Reason for update

Acronym

تأثیر بکار بردن سوزن سرد بر شدت درد ناشی از کانولاسیون فیستول شریانی -وریدی بیماران تحت همودیا لیز

IRCT registration information

IRCT registration number: **IRCT20230902059328N1**

Registration date: **2023-12-10, 1402/09/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-10, 1402/09/19**

Update count: **0**

Registration date

2023-12-10, 1402/09/19

Registrant information

Name

Farzaneh Gerivani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 933 208 6649

Email address

gerivanif4001@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-30, 1402/05/08

Expected recruitment end date

2024-01-30, 1402/11/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of insert a cooled needle on arteriovenous fistula puncture-related pain intensity in hemodialysis patients

Public title
pain relief during venipuncture in hemodialysis patients

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Presence of both arterial and venous fistula At least one month elapsed since the creation of the fistula Full consciousness and ability to articulate pain symptoms Undergoing hemodialysis three time a week Absence of dementia or Alzheimer s disease No active cancer diagnosis Proficiency in the persian language Not currently using anesthesia Having good vision Willingness to participate in the study Ability to communicate pain experiences Stable hemodynamic status Absence of muscle and joint injuries Age 18and above

Exclusion criteria:
Blood pressure below 80/40 mm Hg during fistula cannulation Failure to insert the needle into the fistula on the first occasion Presence of phlebitis at the cannulation site.

Age
From **18 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants Were randomly assigned to either the intervention group (N=30)or the control group (N=30)using the permuted block technique with block sizes of 6 (AABABB-AAABBB-BABABA-ABABAB-BABABA-AAABBB-ABAABB-BBAABA-BBAABA)the assignment was determined by the random selection of blocks, with the letters A and B representing the control and intervention groups, respectively

Blinding (investigator's opinion)
Single blinded

Blinding description
The groups in the raw data are coded

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Dr Kharazmi Complex, Ferdosi University, Park Squre, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9179133859

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.063

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

T85.8

ICD-10 code description

Other specified complications of internal prosthetic devices, implants and grafts, not elsewhere classified

Primary outcomes

1

Description

Pain intensity after needle insertion with normal and cold temperature using 10 degree pain ruler

Timepoint

Session1, 2, 3, 4

Method of measurement

10-point scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

in group A (30), in the first and second sessions, cannulation will be performed with a No. 15 needles at

room temperature, and in the third and fourth sessions, cannulation will be performed with a No. 15 needles cooled in the refrigerator (temperature -8 degrees). At the end, the intensity of the patient's pain After piercing the artery and vein, the pain will be measured and recorded separately with a ruler.

Category

Other

2**Description**

Intervention gln group B (30 people), in contrast to group A, in the first and second sessions, cannulation will be performed with a #15 needle cooled in the refrigerator (temperature -8 degrees) and in the third and fourth session, cannulation will be performed with a #15 needle at room temperature, and the pain intensity will be The patient will be measured and recorded separately after the puncture of the artery and vein.roup:

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mantasarieh Hospital, Mashhad. 17 Shahrivar hospital, Mashhad

Full name of responsible person

Bagheri Maryam

Street address

Shahid Kharazmi Complex, Ferdowsi University of Mashhad, Park Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9179133859

Phone

+98 51 3891 5597

Email

bagherim@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Tafaghodi Mohsen

Street address

Knowledge and Health City - In the end of Shahid Fakouri Blvd (In front of Fakouri ۹۴) - Mashhad - Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

bagheri@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Bagheri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Kharazmi Complex, Ferdowsi University of Mashhad, Park Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9179133859

Phone

+98 51 3891 5597

Email

bagherim@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Bagheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Kharazmi Complex, Ferdowsi University of
Mashhad, Park Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9179133859

Phone

+98 51 3891 5597

Email

bagherim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Bagheri Maryam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Dr Kharazmi complex, Ferdosi University, Park Squire,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9179133859

Phone

+98 51 3891 5597

Email

bagherim@mums.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

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

Informed Consent Form

No - There is not 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

Title and more details about the data/document

publish in journal related hemodylyysi

**When the data will become available and for how
long**

no limitation

To whom data/document is available

researcher, nurses, students

Under which criteria data/document could be used

site of journal, library in school of nursing and midwifery
in Mashhad

From where data/document is obtainable

Maryam bagheri (school of nursing and midwifery in
Mashhad)

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

email: bagherim@mums.ac.ir

Comments