Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 Mantasarieh 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
تاثیر بکار بردن سوزن سرد بر شدت درد ناشی از کانولاسیون فیستول شریانی –وریدی بیماران تحت همودیالیز

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)

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+98 933 208 6649

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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

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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

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Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

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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

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

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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

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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

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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 hemodyilysi

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