

# 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 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)

##### 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**

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**Province**

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**Postal code**

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**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

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**Province**

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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

**Latest degree**

Ph.D.

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**Email**

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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 hemodylysi

**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**