Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison of the effect of cold needle and lidocaine spray on the intensity of pain caused by vascular needles insertion in hemodialysis patients

Protocol summary

Study aim
Determining and comparing the effect of cold needle and lidocaine spray on the intensity of pain caused by the insertion of vascular needles in hemodialysis patients of hospitals covered by Rafsanjan University of Medical Sciences, 2024

Design
A randomized, blinded, controlled clinical trial

Settings and conduct
This study will be conducted on 30 hemodialysis patients referred to the dialysis department of Ali Ibn Abi Talib Rafsanjan and Hazrat Wali Asr Anar hospitals. The order of interventions including lidocaine spray, placebo lidocaine spray, cold needle or being in the control group for each patient is determined by lottery

Participants/Inclusion and exclusion criteria
Using fistula for hemodialysis Not using painkillers or narcotics 6 hours before hemodialysis No neuropathy No blindness and deafness Willingness to participate in the study Not allergic to lidocaine Death Change of residence or travel If the cannulation process is done more than once

Intervention groups
Group cold needle Control group Group 10%lidocaine spray Plasebo group

Main outcome variables
Pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131228015965N24**
Registration date: **2024-09-22, 1403/07/01**
Registration timing: **prospective**
Last update: **2024-09-22, 1403/07/01**
Update count: **0**

Registration date
2024-09-22, 1403/07/01

Registrant information

Name
Majid Kazemi

Name of organization / entity
Rafsanjan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-28, 1403/07/07

Expected recruitment end date
2024-11-09, 1403/08/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of cold needle and lidocaine spray on the intensity of pain caused by vascular needles insertion in hemodialysis patients

Public title
Comparison of the Effect of cold needle and lidocaine spray on the intensity of pain caused by vascular needles

insertion in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Using a fistula for hemodialysis Not using painkillers or narcotics 6 hours before hemodialysis No neuropathy Not allergic to lidocaine Willingness to participate in the study No blindness and deafness

Exclusion criteria:

Using catheter for hemodialysis Any problem in vascular accessibility Peripheral vascular disease Unsuccessful puncture at the first attempt.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient enters the study 4 times and each patient is his own control group. And by a simple randomization method, using a lottery, it is determined for each patient which intervention will be treated in each session. Each intervention or placement in the control group is assigned a number from one to four, then a lottery is conducted for each patient and the order of interventions is determined. For example, patient number one, his first intervention is cold needle, then a week later his second intervention is placebo, then control group and finally lidocaine spray. Or, for example, out of thirty patients, seven of them will have their first cold needle intervention determined by lottery. And five patients, their first intervention is placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the pain evaauator cannot distinguish the container containing lidocaine spray from the container containing distilled water by using two completely similar containers, and the pain evaluator will not know the executive interventions.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd., Medical University Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2024-09-11, 1403/06/21

Ethics committee reference number

IR.RUMS.REC.1403.086

Health conditions studied

1

Description of health condition studied

Pain caused by Vascular needles in hemodialysis patient

ICD-10 code

N18.4

ICD-10 code description

Chronic kidney disease, stage 4 (severe)

Primary outcomes

1

Description

The intensity of pain caused by the insertion of vascular needles

Timepoint

The intensity of pain caused by the insertion of vascular needles will be measured immediately after the intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10% lidocaine spray, two puffs from a distance of five centimeters in the place where the needle is inserted, five minutes before inserting the vascular needles.

Category

Treatment - Drugs

2

Description
Intervention group: Placebo lidocaine spray, which uses distilled water in a container similar to the lidocaine spray container and two puffs from a distance of five centimeters, five minutes before entering the sample of vascular needles
Category
Placebo

3

Description
Intervention group: Fistula cannulation with vascular needles kept at -10_ -13 degrees Celsius for 24 hours
Category
Treatment - Devices

4

Description
Control group: Performing fistula cannulation in the common way in the hemodialysis department
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abi Taleb Hospital and Vali Asr Hospital
Full name of responsible person
Majid kazemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Dr Reza Vazirinejad
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Majid Kazemi
Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available