

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 7663

Email address

dr.kazemi.n@rums.ac.ir

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

Street address

Imam Ali Blvd., Medical University Sciences

City

Rafsanjan and Anar

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

Dr.kazemi.n@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

Street address

Imam Ali Blvd., Medical University Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

Dr.Kazemi.n@rums.ac.ir

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

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Imam Ali Blvd., Medical University Sciences

City

رفسنجان

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

Dr.Kazemi.n@rums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Majid Kazemi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Imam Ali Blvd., Medical University Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

Dr.Kazemi.n@rums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Majid Kazemi

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Imam Ali Blvd., Medical University Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3425 7663

Email

Dr.Kazemi.n@rums.ac.ir

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