# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 Scienes
**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 Sceinces

**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