

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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 evaluator 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

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#### 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

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#### 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

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## 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**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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