

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative assessment the effect of three methods of cold therapy on the pain intensity of vascular needling in patients undergoing hemodialysis

Protocol summary

Study aim

Determining the effect of three methods of cold therapy on the pain intensity of vascular needles in hemodialysis patients

Design

Clinical practice with control group, Double blind, randomized

Settings and conduct

The place of the study is dialysis center of Ali ibn Abitaleb Hospital in Rafsanjan

Participants/Inclusion and exclusion criteria

Inclusion criteria: A history of at least three months of hemodialysis; Being conscious; Being at the age of 18 or more; Patients who are able to diagnose pain assessment; Willing to participate in the study. Exclusion criteria: Any problem in vascular accessibility; Peripheral vascular disease; Unsuccessful puncture at the first attempt; Neuropathy disorders

Intervention groups

The research samples will participate three times in the research. During the hemodialysis, two vessels are taken from the patients. A place will be under the intervention and another place will be placed under the placebo treatment. There will be three interventions and three placebos in this study and in each session one intervention and its relevant placebo will be given to the patient. Therefore, three therapeutic interventions (Mini AIS Cooling Gel, Cold Spray and Ice Compounds) will be performed through three hemodialysis sessions.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131228015965N13**

Registration date: **2019-01-09, 1397/10/19**

Registration timing: **retrospective**

Last update: **2019-01-09, 1397/10/19**

Update count: **0**

Registration date

2019-01-09, 1397/10/19

Registrant information

Name

Majid Kazemi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3425 7663

Email address

dr.kazemi.n@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment the effect of three methods of cold therapy on the pain intensity of vascular needling in

patients undergoing hemodialysis

Public title
The effect of Cold Therapy on pain intensity caused by needles in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 A history of at least three months of hemodialysis Being conscious Being at the age of 18 or more Patients who are able to diagnose pain assessment Willing to participate in the study
Exclusion criteria:
 Any problem in vascular accessibility Peripheral vascular disease Unsuccessful puncture at the first attempt Neuropathy disorders

Age
From **18 years** old to **85 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
By simple randomization method and through lottery, it is determined which intervention should be used in each session.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the participants in the study and the person evaluating the pain are blind to the intervention

Placebo
Used

Assignment
Crossover

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

Rafsanjan University of Medical Sciences, Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717932777

Approval date

2018-05-26, 1397/03/05

Ethics committee reference number

IR.RUMS.REC.1397.054

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

pain

Timepoint

Immediately after importing Needles

Method of measurement

Based on a numerical scale VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: at the entrance of the needle (venous or arterious), an ice pack with dimentions of 2 × 2 × 2 which put inside the glove will use for 3 minutes.

Category

Treatment - Drugs

2

Description

Control group: In the opposite site of intervention 1, a piece of wood with dimentions of 2 × 2 × 2 which put inside a glove will be used for 3 minutes.

Category

Treatment - Drugs

3

Description

Intervention group 2: at the entrance of the needle (venous or arterious), the cold spray (manufactured by Delta-Daroo Pharmaceutical Company) will be sprayed

from a distance of 25 cm for 2 seconds and cannulation will be done after 20 seconds.

Category

Treatment - Drugs

4**Description**

Control group 2: In the opposite site of intervention 2, distilled water spray will be used in the same way as cold spray.

Category

Treatment - Drugs

5**Description**

Intervention group 3: at the entrance of the needle (venous or arterial), 1 cc coolant gel (produced by Oran Arash company) will use and cannulation will done after 4 minutes.

Category

Treatment - Drugs

6**Description**

Control group 3: In the opposite site of intervention 3, 1 cc lubricant gel will be used in the same way as coolant gel.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rafsanjan Ali-ibn Abi-Talib Hospital

Full name of responsible person

Dr. Majid Kazemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**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

Dr. Majid Kazemi

Position

phd

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

No more 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