

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparative study of effect of two methods related to ice massage in Huko point and Valsalva maneuver on pain intensity during needle insertion into arteriovenous fistula of hemodialysis patients

Protocol summary

Summary

Purpose: Comparison of two methods of ice massage in Hoku point and Valsalva maneuver on pain intensity during needle insertion of arteriovenous fistula in hemodialysis patients in selected hospitals in Isfahan in 2015 Study design: non-randomized clinical trial The methods used included: A study population: Main inclusion criteria: patient be alert. hemodialysis is performed Through fistula, patients are older than 18 years of age. The main criteria for exclusion: unwillingness to cooperate, died, inability to perform the Valsalva maneuver, the inability of access to the vessels in the first attempt Sample size: 70 (B) intervention or interventions studied: ice massage in Hoku point in Contralateral hand with fistula, Valsalva maneuver C-time intervention: ice massage is performed 10 min prior to cannulation and during it and Valsalva maneuver 20 seconds before needle insertion or cannulation (D) the primary outcome or consequences of the study: objective and subjective pain intensity during fistula cannulation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081423615N1**
Registration date: **2015-09-18, 1394/06/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-18, 1394/06/27

Registrant information

Name

Elham Davtalab

Name of organization / entity

Islamic Azad University Isfahan(Khorasgan) Branch

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Islamic Azad University Isfahan (Khorasgan) Branch.

Expected recruitment start date

2015-03-05, 1393/12/14

Expected recruitment end date

2015-04-04, 1394/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of effect of two methods related to ice massage in Huko point and Valsalva maneuver on pain intensity during needle insertion into arteriovenous fistula of hemodialysis patients

Public title

Comparison of the effects of ice massage and Valsalva maneuver on pain

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patients in the study are hemodialysis;

dialysis performed from arteriovenous fistula; be willing to participate in the study; older than 18 years; fully conscious and able to answer their questions; verbal and visual communication can be achieved; no severe pain in the body area before inserting the needle into the fistula; history of drug abuse not mentioned; during the 6 hours before hemodialysis is not used analgesics or sedatives; avf cannulation is possible to one try of cannulation; history of diseases such as Alzheimer's, dementia, peripheral vascular disease, diabetic neuropathy disorders not mentioned; heart disease, glaucoma, increased pressure in the brain, the eyes do not have a recent surgery; have not inflammation and damage, redness, pain and bruise on the skin av fistula; does not mention sensitivity to ice massage; be able to perform the Valsalva maneuver and keeping the mercury column manometer to the pressure of 20 mmHg for 20 seconds. Exclusion criteria: the patient's unwillingness to continue participating in the study; Death and absence in the second session to continue treatment; the lack of proper venipuncture every effort in the second session of hemodialysis; the use of a sedative before the start of the second session of hemodialysis; inability to perform the Valsalva maneuver correctly.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences and Health Services

Street address

Hezarjarib Street

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Isfahan

Postal code

81786-73461

Approval date

2015-02-09, 1393/11/20

Ethics committee reference number

293335

Health conditions studied**1****Description of health condition studied**

Hemodialysis patient

ICD-10 code

N18.5

ICD-10 code description

End stage kidney disease

Primary outcomes**1****Description**

Objective pain

Timepoint

Before and immediately after the intervention

Method of measurement

Abbey pain scale

2**Description**

Subjective pain

Timepoint

Before and immediately after the intervention

Method of measurement

Numerical Rating Scale 0-10

Secondary outcomes**1****Description**

Blood pressure and pulse rate

Timepoint

10 minute prior of cannulation and 5 minute after the cannulation

Method of measurement

Heart and blood pressure monitoring device

Intervention groups**1****Description**

"control group: After disinfection of the arteriovenous fistula, without performing any action, inserting needle in to av fistula in contralateral hand with av fistula, was done."

Category

Other

2

Description

" intervention group: Using an ice ball with a diameter of 1.5-2 cm, was wrapped in a plastic glove, the space between the thumb and forefinger of cotralateral hand with fistula, 10 minutes before and 2 minutes during insertion of needle in to the avf,circular was massaged. "

Category

Other

3

Description

"intervention group: The patients were asked to blow in the hole of disposable syringe that is placed in one side plastic tube manometer and the other end of tube, was connected to the sphygnomanometer and lift mercury column up to 20 mm Hg and maintain height of the mercury column for 20 seconds to 20 mmHg. 20 seconds after, inserting needle in arteriovenous fistula was performed."

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Majesty Zahra Hospital

Full name of responsible person

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Reaserch of Islamic Azad University Isfahan

Full name of responsible person

DR Arash Ghoddousi

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NO.48;Shahid Sheikhi; Shahid Vaezi Street; Valashan; Dorcheh

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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

Vice Chancellor for Reaserch of Islamic Azad University Isfahan

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University Isfahan (Khorasgan) Branch

Full name of responsible person

Elham Davtalab

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty