

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3375 0848

##### Email address

e.davtalab@khuif.ac.ir

##### 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 no 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

**City**

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

Elham Davtalab, MS of Nursing Education

##### Street address

Bigining Alameh Majlesi Street

##### City

Isfahan

### 2

#### Recruitment center

##### Name of recruitment center

Amin Hospital-Isfahan

##### Full name of responsible person

Elham Davtalab, MS of Nursing Education

##### Street address

Amin Hospital-Isfahan, Shohada Squire, Ebne Sina Street

##### City

Isfahan

## 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

##### Street address

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

##### City

Khomeini Shahr

##### 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

#### Position

MS of Nursing Education

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

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Seyed Ali Naji

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PHD

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University Isfahan (Khorasgan) Branch;  
Faculty of Nursing and Midwifery  
**Full name of responsible person**  
Elham Davtalab  
**Position**  
MS of Nursing Student  
**Other areas of specialty/work**  
**Street address**  
Arghavanieh Blvd; East J Street  
**City**  
Khorasgan

## 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*