Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The effect of valsalva maneuver and distraction on pain intensity during vascular needle insertion in hemodialysis patients

Protocol summary

Study aim
Determining the effect of Valsalva maneuver and distraction on pain intensity during vascular needle insertion in hemodialysis patients.

Design
A clinical trial with a control group, one-way blind, single-center trial, randomized, 30 participants in 3 groups of 10 people.

Settings and conduct
Hemodialysis Center of Imam Ali Karaj Hospital Pain intensity when inserting arterial needles is measured in 3 modes (Valsalva maneuver, distraction, and routine care). The participating person and the person who performs the statistical analysis do not know about the intervention modes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 and above; Performing hemodialysis through an arteriovenous fistula; At least three months have passed since the start of hemodialysis through the fistula Exclusion Criteria: Injury or lesion in the hand with fistula; Patients who are unable to perform the Valsalva maneuver by keeping the mercury column higher than 20 mmHg for 20 seconds; Failure to take a vein from the person in the first attempt

Intervention groups
Intervention group 1: In this group (Valsalva maneuver), according to the protocol, the patient blew into a disposable plastic tube connected to a mercury sphygmomanometer, and keeps the mercury column up to 20 mm Hg for at least 15 seconds. after the intervention, the arterial needle is inserted into the vessels near the fistula site and after one minute after being fixed, the pain intensity is measured. Intervention group 2: In this group (thought deviation), according to the protocol, one minute before the intervention, the patient holds a soft pressure ball in his opposite hand and presses it by opening and closing his hand and starts counting, and it continues for one minute after entering the arterial needle. Control group: No treatment is done and only routine treatment is done.

Main outcome variables
Pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N81**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

Registration date
2024-01-17, 1402/10/27

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of valsalva maneuver and distraction on pain intensity during vascular needle insertion in hemodialysis patients

Public title
The effect of valsalva maneuver and distraction on pain intensity during vascular needle insertion in hemodialysis patients
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 and above Minimum literacy to recognize numbers Performing hemodialysis through an arteriovenous fistula At least three months have passed since the start of hemodialysis through the fistula Absence of simultaneous pain in other parts of the body Not receiving drugs and painkillers from 6 hours ago
Exclusion criteria:
Injury or lesion in the hand with fistula Patients who are unable to perform the Valsalva maneuver by keeping the mercury column higher than 20 mmHg for 20 seconds. Failure to take a vein from the person in the first attempt The presence of phlebitis at the site of the fistula Patients with a history of cardiovascular disease (bradycardia, hypotension, and CHB) and cerebrovascular disease
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 3). Using Sealed Envelope software to generate random number tables
Blinding (investigator's opinion)
Single blinded
Blinding description
The participating person and the person who performs the statistical analysis do not know about the intervention modes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2023-10-30, 1402/08/08
Ethics committee reference number
IR.SEMUMS.REC.1402.175

Health conditions studied

1

Description of health condition studied
Pain intensity
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Pain intensity
Timepoint
One minute after inserting the arterial needle and fixing it
Method of measurement
Numeric Pain Rating Scale (NRPS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group (Valsalva maneuver), according to the protocol, the patient blew into a disposable plastic tube connected to a mercury sphygmomanometer (Easy Life, TXJ-10B model, China).

and keeps the mercury column up to 20 mm Hg for at least 15 seconds. after the intervention, the arterial needle is inserted into the vessels near the fistula site and after one minute after being fixed, the pain intensity is measured.

Category

Treatment - Other

2

Description

Intervention group: In this group (thought deviation), according to the protocol, one minute before the intervention, the patient holds a soft pressure ball in his opposite hand and presses it by opening and closing his hand and starts counting, and it continues for one minute after entering the arterial needle.

Category

Treatment - Other

3

Description

Control group: No treatment is done and only routine treatment is done. It is only for comparison with the intervention group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Hemodialysis Center of Imam Ali Karaj Hospital

Full name of responsible person
Mansour Azarian

Street address
Three ways azimieh, Karaj

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Karaj

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Alborz

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1418946846

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Fatemeh Ehsani

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Mohammadreza Asgari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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