Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison of Valsalva maneuver and Rhythmic breathing in terms of their effectiveness on the pain of vascular needles insertion in hemodialysis patients

Protocol summary

Study aim

This study aimed to compare the effect of Valsalva maneuver and Rhythmic breathing on the severity of pain caused by fistula cannulation.

Design

An unblinded , controlled, parallel-group, randomized clinical trial on 90 hemodialysis patients using sealed envelopes containing the letters A, B and C in equal numbers, where A represents Valsalva maneuver, B represents Rhythmic breathing, and C represents the control group.

Settings and conduct

This study will be conducted in the hemodialysis department of Kawsar Semnan Hospital. In the Valsalva maneuver group, after blowing into a plastic tube connected to a mercury pressure gauge, perform the Valsalva maneuver for at least 20 seconds, and then fistula cannulation will be performed. In the second group, first the patient closes his eyes, lies on his back and inhales through the nose by counting the numbers from 1 to 3, then holds his breath by counting the numbers 1 to 3 again and counting the numbers Exhales 1 to 3 through the mouth. This work will be done for 20 minutes, every 5 minutes and each time for 1 minute. Fistula cannulation will be performed in the same conditions as the first group. No special action will be taken in the control group and fistula cannulation will be done in the same way as the previous two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: hemodialysis started at least 3 months ago; no addiction and dependence on painkillers; no pain before cannulation; no use of sedatives in the last 24 hours; no wound in the fistula area. Exclusion criteria: unsuccessful cannulation in the first step and repeated insertion of the needle into the skin.

Intervention groups

The study will be performed on two groups of interventions, including Valsalva maneuver or Rhythmic breathing, and one control group, without any specific intervention.

Main outcome variables

Pain severity due to fistula cannulation

General information

Reason for update

Because blinding was not possible in this study and patients in the Valsalva maneuver, rhythmic breathing, and control groups were clearly aware of the type of intervention, blinding was changed from double-blind to unblinded.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120109008665N16**
Registration date: **2024-03-14, 1402/12/24**
Registration timing: **prospective**

Last update: **2025-04-08, 1404/01/19**
Update count: **1**

Registration date

2024-03-14, 1402/12/24

Registrant information

Name

Hassan Babamohamadi

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-04-08, 1403/01/20
Expected recruitment end date
2024-08-20, 1403/05/30
Actual recruitment start date
2024-04-08, 1403/01/20
Actual recruitment end date
2024-10-21, 1403/07/30
Trial completion date
2024-11-05, 1403/08/15

Scientific title
Comparison of Valsalva maneuver and Rhythmic breathing in terms of their effectiveness on the pain of vascular needles insertion in hemodialysis patients

Public title
Comparative study of Valsalva maneuver and Rhythmic breathing on pain intensity due to fistula cannulation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years History of at least 3 months of hemodialysis No addiction or dependence on painkillers No pain before cannulation Do not use the sedative at the last 24 hours No wounds in the fistula area Not treated with sulfonamides, nitrates and phenobarbital Not having a pacemaker No history of Alzheimer's disease, dementia, peripheral vascular disease, diabetic neuropathy, liver disease Lack of respiratory problems, brain problems, glaucoma, increased intracranial pressure and recent eye surgery
Exclusion criteria:
Patients who are unable to perform the Valsalva maneuver by holding the mercury column above 20 mm Hg for 20 seconds Unsuccessful cannulation in the first step and repeated insertion of the needle into the skin Patients with known heart attack or those with hemodynamic problems or dangerous arrhythmias
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to three groups using the random blocks method and by 90 sealed envelopes containing one of the letters A, B and C in an equal number (30 envelopes of each letter) where A represents Valsalva maneuver, B represents rhythmic breathing and C represents the control group. Patients will select the envelope themselves.
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
Semnan University of Medical Sciences
Street address
Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran
City
Semnan
Province
Semnan
Postal code
3519899951
Approval date
2024-02-10, 1402/11/21
Ethics committee reference number
IR.SEMUMS.REC.1402.276

Health conditions studied

1

Description of health condition studied
Acute pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
The severity of the pain
Timepoint
The first stage without intervention - the second stage after the intervention
Method of measurement
Numerical Pain Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Valsalva maneuver in the first group was accomplished through blowing in a plastic pipe connected to a mercury barometer (Easylife, china) and holding up mercury bar upper than 20 mmHg for at least 20 seconds. After the place was disinfected using cotton drained in alcohol. Then, BP16 IVC was used to do fistula cannulation while the patient lay back and his head is against the cannulation point.

Category
Treatment - Other

2

Description
Intervention group: Patients of the second group (rhythmic breathing) in order to perform the intervention, first the patient closes his eyes, lies on his back and breathes through the nose by counting the numbers from 1 to 3, Then he/she held his/her breath by counting the numbers 1 to 3 again. He/she locks himself/herself and exhales through the mouth by counting the numbers 1 to 3. This work will be done for 20 minutes, every 5 minutes and each time for 1 minute. Fistula cannulation will be performed under the same conditions as the first group.

Category
Treatment - Other

3

Description
Control group: In the third group (control), there will be no special intervention. Fistula cannulation will be performed under the same conditions of the two intervention groups.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar hospital affiliated to Semnan University of Medical Sciences

Full name of responsible person
Hassan Babamohamadi

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Kowsar Hospital, Amin Blv, Golestan town, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Majid Mirmohammadkhani

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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
Hassan Babamohamadi

Position
Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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