Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

"The effects of diaphragmatic and resonance breathing techniques on physiological indices and pain intensity during arteriovenous fistula cannulation in hemodialysis patients"

Protocol summary

Study aim

-Pain intensity in 3 groups during cannulation - Systolic and diastolic blood pressure, heart rate, and respiratory rate in 3 groups 0, 1, 5, and 10 minutes after the intervention

Design

Crossover clinical trial with 2 intervention groups and 1 control group - 135 patients - 6-block randomization

Settings and conduct

• Diaphragmatic breathing: Lie on your back on the bed for 5 minutes and place a pillow under your head and knees - Place one hand on your chest and the other on your stomach - Inhale through your nose and exhale through your mouth - Rest for 5 minutes • Resonance breathing group: Place the patient in a semi-sitting position at a 45-degree angle, place one hand on your stomach and the other on your diaphragm - Take 5 deep breaths per minute using your diaphragm • Control group: Receive routine hospital care

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Consciousness 2- Age over 18 years 3- Absence of neuropathic disorders and peripheral vascular diseases 4- Absence of respiratory diseases (COPD, asthma) 5- Successful cannulation in the first attempt Exclusion criteria: 1- Development of respiratory problems during the study 2- Development of a critical life-threatening condition during the study 3- Death of the patient, change in the treatment process such as transplantation

Intervention groups

- Diaphragmatic breathing group - Resonance breathing group - Control group

Main outcome variables

1. Pain level 2. Systolic blood pressure 3. Diastolic blood pressure 4. Mean Arterial Pressure 5. Pulse rate 6. Respiratory rate 7. Oxygen Saturation (SaO2)

General information

Reason for update

Acronym

DRBT

IRCT registration information

IRCT registration number: **IRCT20250730066695N2**
Registration date: **2025-08-13, 1404/05/22**
Registration timing: **prospective**

Last update: **2025-08-13, 1404/05/22**
Update count: **0**

Registration date

2025-08-13, 1404/05/22

Registrant information

Name

Behzad Imani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1014

Email address

behzadiman@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-01-21, 1404/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
"The effects of diaphragmatic and resonance breathing techniques on physiological indices and pain intensity during arteriovenous fistula cannulation in hemodialysis patients”

Public title
"The effect of diaphragmatic and resonance breathing techniques on arteriovenous fistula in hemodialysis patients"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a history of hemodialysis through a fistula for at least three months, at least twice a week Being conscious Age 18 to 75 years No problems in accessing the vessels and no neuropathic disorders and peripheral vascular diseases No respiratory diseases (COPD, asthma, etc.)

Exclusion criteria:
Life-threatening critical condition Unsuccessful cannulation on the first attempt

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done on a convenience basis, but the allocation of diaphragmatic breathing, resonant breathing, and cannulation control will be done using a 6-block randomization method as ABC-ACB-BCA-BAC-CAB-CBA. In this way, a sequence of the above blocks will be randomly generated using R software, and a list will be created, and patients will be randomly assigned to one of the three groups based on the aforementioned list.

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyzer responsible for evaluating the trial's results will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a single-blind study.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Ghaem Square, Shahid Fahmideh Street,Hamadan University of Medical Sciences

City
Hamadan

Province
Hamadan

Postal code
6517838741

Approval date
2025-07-26, 1404/05/04

Ethics committee reference number
IR.UMSHA.REC.1404.312

Health conditions studied

1

Description of health condition studied
hemodialysis patients

ICD-10 code
Z49.02

ICD-10 code description
Encounter for fitting and adjustment of peritoneal dialysis catheter

Primary outcomes

1

Description
The amount of pain felt by the patient is determined using the Numeric Rating Scale scale on a scale from 0 to 10.

Timepoint
The intensity of patients' pain during the insertion of arterial and venous needles (in the two stages of cannulation) will be measured by an experienced dialysis nurse for all groups.

Method of measurement
Assessment of patient pain from two cannulation lines using the Numeric Rating Scale by a nurse who is unaware of the study groups.

2

Description
Oxygen saturation percentage measured with a pulse oximeter.

Timepoint

The measurement is performed in such a way that after the patient lies down on the bed and rests for 3 minutes, the oxygen saturation percentage will be measured.

Method of measurement

Physiological indicators including oxygen saturation percentage, blood pressure (systolic, diastolic, Mean atrial pressure), heart rate, and respiratory rate will be recorded through a monitoring device by a nurse who is unaware of the study groups.

3

Description

Systolic blood pressure is the blood pressure during the contraction phase of the heart, which is recorded as a number in millimeters of mercury based on the monitoring device.

Timepoint

The measurement is done in such a way that after the patient lies down on the bed and rests for 3 minutes, systolic blood pressure will be measured.

Method of measurement

Physiological indicators including oxygen saturation percentage, blood pressure (systolic, diastolic, Mean atrial pressure), heart rate, and respiratory rate will be recorded through a monitoring device by a nurse who is unaware of the study groups.

4

Description

Diastolic blood pressure is the blood pressure during the resting phase of the heart, which is recorded as a number and in millimeters of mercury based on the monitoring device.

Timepoint

The measurement is done in such a way that after the patient lies down on the bed and rests for 3 minutes, the diastolic blood pressure will be measured.

Method of measurement

Physiological indicators including oxygen saturation percentage, blood pressure (systolic, diastolic, Mean atrial pressure), heart rate, and respiratory rate will be recorded through a monitoring device by a nurse who is unaware of the study groups.

5

Description

Mean atrial pressure= + (2 × diastolic pressure)] (systolic pressure)] / 3which is recorded as a number based on the monitoring device.

Timepoint

The measurement is done in such a way that after the patient lies down on the bed and rests for 3 minutes, the Mean atrial pressure pressure will be measured.

Method of measurement

Physiological indicators including oxygen saturation percentage, blood pressure (systolic, diastolic, Mean atrial pressure), heart rate, and respiratory rate will be recorded through a monitoring device by a nurse who is unaware of the study groups.

6

Description

The number of heartbeats per minute, which is monitored and recorded by a vital signs monitoring device.

Timepoint

The measurement is performed in such a way that after the patient lies down on the bed and rests for 3 minutes, the number of heart beats per minute will be measured.

Method of measurement

Physiological indicators including oxygen saturation percentage, blood pressure (systolic, diastolic, Mean atrial pressure), heart rate, and respiratory rate will be recorded through a monitoring device by a nurse who is unaware of the study groups.

7

Description

The number of breaths per minute, which is monitored and recorded by a vital signs monitoring device.

Timepoint

The measurement is done in such a way that after the patient lies down on the bed and rests for 3 minutes, the number of breaths per minute will be measured.

Method of measurement

Physiological indicators including oxygen saturation percentage, blood pressure (systolic, diastolic, Mean atrial pressure), heart rate, and respiratory rate will be recorded through a monitoring device by a nurse who is unaware of the study groups.

Secondary outcomes

1

Description

Pain score

Timepoint

During cannulation

Method of measurement

Numeric Rating Scale

2

Description

Mean systolic and diastolic blood pressure

Timepoint

0, 1, 5 and 10 minutes after intervention

Method of measurement

Vital signs monitoring device

3

Description

Pulse and respiration rate

Timepoint

0, 1, 5 and 10 minutes after intervention

Method of measurement

Vital signs monitoring device

Intervention groups

1

Description
Intervention group 1: Diaphragmatic breathing technique for 5 minutes during three hemodialysis sessions
Category
Treatment - Other

2

Description
Intervention group 2: Resonance breathing technique for 5 minutes during three hemodialysis sessions.
Category
Treatment - Other

3

Description
Control group: Control group: Routine hospital care
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti medical center, Hamadan
Full name of responsible person
Amir hossein Asadi
Street address
Ghaem Square _ Beginning of Eram Boulevard Shahid Beheshti Specialized and Subspecialized Medical Training Center- HAMADAN
City
Hamadan
Province
Hamadan
Postal code
6517837741
Phone
+98 81 3838 0704
Email
Amirasadi1977@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
Street address
Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 4047
Fax
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Amir Hossein Asadi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 1014
Email
Amirasadi1977@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person
Arezou Karampourian

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 1014

Email
karampor1@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Behzad Imani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Faculty of Para medicine, Department of Operating Room, Hamadan University of Medical Sciences, Hamadan

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 1017

Email
behzadiman@yahoo.com

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

Informed Consent Form
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available

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