Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of active cycle breathing technique on pain, anxiety and blood oxygen saturation of patients undergoing coronary artery bypass graft (CABG)

Protocol summary

Study aim
Determining the effect of active breathing cycle technique on pain, anxiety and saturation Arterial blood oxygen in patients undergoing coronary bypass surgery

Design
Parallel group randomized trial in which participants will be divided into two groups by permuted block randomization. Sample size was calculated 76.

Settings and conduct
After referring to the CCU and heart departments of Al-Zahra Heart Hospital in Shiraz, the researcher selects people according to the entry and exit criteria and includes them in the study if they give informed consent. In the intervention group, in addition to receiving routine care, breathing exercises are taught to the patients one day before the surgery by the researcher or the researcher's assistant, and after surgery and extubation, breathing exercises are taught on two consecutive days in two shifts, morning and evening. It is done with the guidance of the researcher. Patients in the control group will receive routine care, including the use of an incentive spirometer. In the intervention group, anxiety, pain and arterial blood oxygen saturation will be assessed once before the intervention and then after each time the active breathing cycle technique is performed. In the control group, the variables will be measured in the same time intervals.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age who need coronary artery bypass surgery as determined by the doctor and have no history of open heart surgery

Intervention groups
In both groups, on the second day after the operation and extubation, all the variables will be measured, then in the intervention group active breathing cycle technique and in the control group, routine interventions will be performed. In both groups, all the variables will be measured. after interventions.

Main outcome variables
pain, anxiety, and blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190727044347N6**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **prospective**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date
2023-10-18, 1402/07/26

Registrant information

Name
Fatemeh Shirazi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of active cycle breathing technique on pain, anxiety and blood oxygen saturation of patients undergoing coronary artery bypass graft (CABG)

Public title
the effect of active cycle breathing technique on pain, anxiety and blood oxygen saturation of patients undergoing coronary artery bypass graft (CABG)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Candidate for coronary artery bypass surgery according to physician's diagnosis Not having a known history of severe respiratory and lung disease Ability to perform breathing exercises and use the active cycle of breathing No previous history of open heart surgery Not having a history of known mental illness or under treatment with anti-anxiety and sedative drugs before surgery
Exclusion criteria:
Unwillingness to stay in the study Occurrence of critical complications after surgery including shock, critical hypertension crisis, cardiac tamponade The occurrence of dangerous dysrhythmias such as atrial fibrillation and ventricular tachycardia Mechanical ventilation for more than 48 hours after surgery The need for reoperation during the hospitalization period
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting eligible individuals to participate in the study based on inclusion criteria, these individuals will be assigned to two study groups based on double randomized permutation block with foursome blocks. The random list is generated by a statistician using "Random Allocation" software. Foursome blocks are the combination of different status such as: ABBA, BAAB, BABA, ABAB, BBAA, AABB. Using random list that is generated by computer,19 blocks will be selected to forme the two study groups.
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
Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information s
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-06-17, 1402/03/27
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.073

Health conditions studied

1

Description of health condition studied
patients undergoing coronary artery bypass graft (CABG)
ICD-10 code
T82.8
ICD-10 code description
Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description
pain
Timepoint
From the second day after surgery and extubation, once before starting the intervention and then after performing each phase of the active breathing cycle technique
Method of measurement
visual analoge of scale pain

2

Description
anxiety

Timepoint
From the second day after surgery and extubation, once before starting the intervention and then after performing each phase of the active breathing cycle technique
Method of measurement
Spielberger questionnaire

3

Description
Oxygen saturation of arterial blood
Timepoint
From the second day after surgery and extubation, once before starting the intervention and then after performing each phase of the active breathing cycle technique
Method of measurement
Pulse oximetry device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In the intervention group, breathing exercises are taught to the patients one day before the surgery by the researcher or the researcher's assistant. From the second day after the surgery and extubation, in the morning and evening shifts, the patients are encouraged to use incentive spirometry as a routine care. They also practice and implement the active cycle of breathing technique. This technique is performed in three stages; The first step is breathing control. At this stage, breathing is done slowly through the nose. If it is not possible for the patient to breathe through the nose, it is done through the mouth with pursed lips. During this stage, the patient is encouraged to keep his peace by closing his eyes and keeping himself away from any tension. The second step is to practice expanding the chest wall to provide airflow in the small airways. At this stage, air flows deeply, slowly and continuously through the nose into the lungs, so that the chest wall expands. The air is held for 2 to 3 seconds and then slowly exhaled through the mouth. This step is repeated 3 times. The final stage is the coughing stage and an integral part of this technique. In this stage, coughing is done through the mouth and throat. For this purpose, the patient takes a deep breath with the mouth open and with the help of respiratory muscles and then coughs. Active breathing cycle technique will be perform from the day after extubation of each patient in two days and in two shifts, morning and evening. Each time will be 3 sessions and each session will last for 10 minutes with a 15 minute break between them. In addition to the active breathing cycle technique, the patients in the intervention group will receive routine care including the use of an incentive spirometer. The level of anxiety, pain and arterial blood oxygen saturation will be assessed by the researcher or research assistant once before the intervention and then after each time the active breathing cycle technique is performed.
Category
Treatment - Other

2

Description
Control group:In the control group, patients receive the usual care, which includes the use of an incentive spirometer, according to the hospital routine. Breathing with a spirometer takes 10 to 20 deep breaths in each shift; This breathing is done in such a way that after the end of inhalation, the patient holds his breath for three seconds and by removing the device, exhales slowly through the mouth. This breathing exercise is performed in every shift until the patient is discharged. It is done sitting or semi-sitting, and after performing this technique, the level of anxiety, pain, and oxygen saturation of the arterial blood of the patients is measured from the day after the extubation of each patient in two days and in two shifts, morning and evening, by the researcher or the researcher's assistant
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Heart Charity Hospital
Full name of responsible person
Dr Hojjatollah Roosta
Street address
Astaneh Three Ways, Sibouyeh Blvd.
City
shiraz
Province
Fars
Postal code
71649-54937
Phone
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Web page address
https://hfhc.sums.ac.ir/?sub=51

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammad Hashem Hashempur
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Vice-Chancellor for Research, Shiraz University of

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Shirazi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position
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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
Not applicable

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable