Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of yoga breathing exercises on respiratory and hemodynamic indicators of patients after coronary artery bypass graft surgery: a Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of yoga breathing exercises on respiratory and hemodynamic indicators of patients after coronary artery bypass surgery

Design

A clinical trial with a control group, without blinding, randomized on 56 patients, the randomization list is created by the web-based software.

Settings and conduct

56 coronary graft surgery patients hospitalized in the special care department of Rajaei Cardiovascular Center will be randomly divided into two intervention and control groups. The control group will receive the breathing rehabilitation routine program and the intervention group will receive yoga breathing exercises in addition to the routine program.

Participants/Inclusion and exclusion criteria

extubated patients who underwent elective coronary artery bypass surgery with the consent of participating in the study and cardiac output fraction > 35%, in the age range of 30-70 years and not on dialysis who were intubated for less than 24 hours. and COPD patients who are not in stage 4 according to FEV1 before the operation. Criteria for non-entry: Reluctance or withdrawal from participating in the study or patients who become hemodynamically unstable during exercise or return to the operating room or patients to have cardiac arrhythmia.

Intervention groups

The control group is subjected to a routine rehabilitation program after surgery, which includes breathing physiotherapy and incentive spirometry, and the intervention group, in addition to receiving the routine program, yoga breathing exercises that include three breathing exercises: 1- Complete breathing, 2- Kapalabathi breathing, and 3- Nadi Shodana breathing. will receive .

Main outcome variables

The primary endpoint includes peak flowmetry, secondary endpoints include respiratory rate, arterial oxygen saturation percentage, heart rate, blood pressure, arterial blood gas indices and outcomes related to patient safety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240313061281N1**
Registration date: **2024-05-23, 1403/03/03**
Registration timing: **prospective**

Last update: **2024-05-23, 1403/03/03**
Update count: **0**

Registration date

2024-05-23, 1403/03/03

Registrant information

Name

Mahnaz Moradi

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-28, 1403/03/08

Expected recruitment end date
2024-11-20, 1403/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of yoga breathing exercises on respiratory and hemodynamic indicators of patients after coronary artery bypass graft surgery: a Randomized Clinical Trial

Public title
Investigating the effect of yoga breathing exercises on respiratory and hemodynamic indicators of patients after coronary artery bypass graft surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Extubated patients who undergo elective coronary artery bypass surgery and have not undergone emergency coronary artery bypass surgery Consent to participate in the study Patients with cardiac output fraction > 35% Patients in the age range of 30-70 years Non-dialysis patients Patients who are intubated for less than 24 hours. COPD patients who are not in stage 4 according to FEV1 before surgery (stage 4-very severe-FEV1 ≤30%).
Exclusion criteria:
Unwillingness or withdrawal from the study at any time Patients who experience unstable hemodynamic conditions during exercise (heart rate above 100 or below 50, systolic pressure drop below 100, dizziness or restlessness, loss of consciousness and respiratory distress with a respiratory rate above 24) Patients who return to the operating room due to bleeding, tamponade and unstable conditions Patients who suffer from cardiac arrhythmia
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Random block method with block size 4 is used for random allocation. The random list will be created by the web-based software and the results will be provided to the principal investigator in sealed envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Rajaie Cardiovascular, Medical and Research Institiue
Street address
NO.1115119969, valiasr St., Hashemi Rafsanjani Hwy, Tehran
City
Tehran
Province
Tehran
Postal code
1996911151
Approval date
2024-05-11, 1403/02/22
Ethics committee reference number
IR.RHC.REC.1403.019

Health conditions studied

1

Description of health condition studied
Patients after coronary artery bypass graft surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of peak flowmeter
Timepoint
in four times, before the intervention and 2 hours after the intervention on the first to fourth days
Method of measurement
Peak flowmeter device

Secondary outcomes

1

Description
Respiratory rate per minute
Timepoint
before the intervention and two hours after training on the first and second days

Method of measurement
Observation of the patient's chest

2

Description
Arterial oxygen saturation percentage
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
Pulse Oximeter

3

Description
Heart rate
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
Pulse Oximeter

4

Description
Systolic and diastolic arterial blood pressure
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
Saadat brand monitor blood pressure gauge

5

Description
partial pressure of carbon dioxide
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
It is performed via arterial blood gas

6

Description
partial pressure of oxygen
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
It is performed via arterial blood gas

7

Description
base excess
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
It is performed via arterial blood gas

8

Description
Bicarbonate
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
It is performed via arterial blood gas

9

Description
potential of hydrogen
Timepoint
before the intervention and two hours after training on the first and second days
Method of measurement
It is performed via arterial blood gas

10

Description
safety endpoints and complications
Timepoint
During the patient's hospitalization
Method of measurement
Observation of patient

Intervention groups

1

Description
Intervention group: In addition to receiving the routine program, the intervention group will receive yoga breathing exercises that include three breaths: 1- Complete breathing, 2- Kapalabhati breathing, and 3- NadiShodhana breathing during four days. Cardiovascular indicators (systolic blood pressure, diastolic blood pressure, heart rate) (and respiratory) respiratory rate, PFM, percentage of oxygen saturation and the values obtained from the interpretation of arterial blood gases including PH, HCO3, PO2, PCO2, BE) before the intervention and 2 hours after the first and 2 hours after the second intervention in the ICU. In addition, two other times of intervention and only the measurement of the peak flowmeter will be done 2 hours after the intervention, after leaving the ICU and in the ward on the third and fourth days after the surgery.
Category
Prevention

2

Description
Control group:they are subjected to a routine rehabilitation program after CABG surgery, which includes respiratory physiotherapy and incentive spirometry. The cardiovascular and respiratory indicators of the control group are also measured at the same time as the intervention group.
Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaei Cardiovascular, Medical and Research Institute

Full name of responsible person
Mahnaz Moradi

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NO.1115119969, valiasr St., Hashemi Rafsanjani Hwy, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Rajaei Cardiovascular, Medical and Research Institute

Full name of responsible person
Saeedeh Mazloumzadeh

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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
Shahid Rajaei Cardiovascular, Medical and Research Institute

Proportion provided by this source
100

Public or private sector
Private

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
Shahid Rajaei Cardiovascular, Medical and Research Institute

Full name of responsible person
Mahnaz Moradi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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No.45, Akbarzare Alley, Golkhane St, Khane isfahan Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rajaie Cardiovascular Medical and Research Center

Full name of responsible person
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
Access starts 6 months after results are published
To whom data/document is available
Data will be available to researchers working in academic and scientific institutions and people working in industry.
Under which criteria data/document could be used
Performing all analyzes on the delivered data is allowed.
From where data/document is obtainable
Email to 'MahnazMoradi 628@gmail.com' This email is owned by Mahnaz Moradi.
What processes are involved for a request to access data/document
The applicant should send request, which includes the reason and motive for accessing the documents and data files, to the mentioned email address. After reviewing the request, the documents will be sent within a few days.
Comments