

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 31 3420 4313

Email address

mahnazmoradi628@gmail.com

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 $\leq$ 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 Institute

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

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular, Medical and Research Institute

Full name of responsible person

Mahnaz Moradi

Street address

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

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

Mahnazmoradi628@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajaei Cardiovascular, Medical and Research Institute

Full name of responsible person

Saeedeh Mazlounzadeh

Street address

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

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

Mahnazmoradi628@gmail.com

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8194957966

Phone

0098314204313

Email

Mahnazmoradi628@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Mahnaz Moradi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8194957966

Phone

+98 31 3420 4313

Fax**Email**

mahnazmoradi628@gmail.com

Person responsible for updating data**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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8194957966

Phone

0098314204313

Email

Mahnazmoradi628@gmail.com

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