

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 ≤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

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

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**Postal code**

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**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, HCO<sub>3</sub>, PO<sub>2</sub>, PCO<sub>2</sub>, 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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## 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

**Street address**

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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****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**