Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of different respiratory rehabilitation protocols on cardiac recovery and hemodynamic parameters before and after coronary artery bypass graft surgery (CABG).

Protocol summary

Study aim
Investigating the effect of different respiratory rehabilitation protocols on cardiac recovery and hemodynamic parameters before and after coronary artery bypass graft surgery (CABG).

Design
Clinical trial with control group, unblinded, randomized, with parallel groups, on 75 patients. A table of random numbers was used for randomization.

Settings and conduct
This study is carried out as a clinical trial on 75 patients who are candidates for coronary artery bypass surgery, referring to Masih Deneshvari Hospital in Tehran, Iran. Patients who meet the study entry criteria will be placed in one of the study groups after providing full explanations and signing a written consent form.

Participants/Inclusion and exclusion criteria
Inclusion criteria include all patients who are candidates for coronary artery bypass surgery, exclusion criteria include age over 70 years, left main coronary artery (LMCA) lesion, history of MI, chest pain during exercise, and ECG changes during exercise.

Intervention groups
The first group includes patients who do not receive respiratory rehabilitation exercises before and after surgery (control group). The second group includes patients who perform respiratory rehabilitation exercises only after surgery. The third group includes patients who perform respiratory rehabilitation exercises before and after surgery.

Main outcome variables
Cardiac output, end-diastolic volume, end-systolic volume, left ventricular dimensions at the end of diastole, left ventricular dimensions at the end of systole, left ventricular extensor index, 6-minute walking test distance, resting heart rate, oxygen saturation at rest, maximum heart rat, VO2 max, fatigue level during activity, dyspnea

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230417057933N1**
Registration date: **2023-04-27, 1402/02/07**
Registration timing: **prospective**

Last update: **2023-04-27, 1402/02/07**
Update count: **0**

Registration date
2023-04-27, 1402/02/07

Registrant information
Name
Zargham_Hossein Ahmadi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2023-11-22, 1402/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of different respiratory rehabilitation protocols on cardiac recovery and hemodynamic parameters before and after coronary artery bypass graft surgery (CABG).

Public title
The effect of different respiratory rehabilitation protocols in patients undergoing coronary artery bypass graft surgery (CABG).

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
All Coronary artery patients candidate for Coronary Artery Bypass Graft (CABG) surgery
Exclusion criteria:

Age
To **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method, individual randomization unit and random number table randomization tool. For randomization, we use a table consisting of random digits from 0 to 9. Each of the figures in this table is repeated the same on average. In this method, each figure is assigned to a treatment group. We start from the first row of the table and move down row by row. For three groups, we put numbers 1 to 3 for the first group, numbers 4 to 6 for the second group, and numbers 7 to 9 for the third group. We continue the above process until three groups are completed.

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
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1956944413

Approval date
2023-04-07, 1402/01/18

Ethics committee reference number
IR.SBMU.NRITLD.REC.1402.002

Health conditions studied

1

Description of health condition studied
Coronary artery bypass surgery

ICD-10 code
I25.709

ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris

Primary outcomes

1

Description
Cardiac output

Timepoint
At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement
Eco cardiography

2

Description
End-diastolic volume

Timepoint
At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement
Eco cardiography

3

Description
Resting heart rate

Timepoint
At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement
Cardiopulmonary exercise test

4

Description
VO2 max
Timepoint
At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery
Method of measurement
Cardiopulmonary exercise test

5

Description
Fatigue during activity
Timepoint
At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery
Method of measurement
Borg scale

6

Description
Dyspnea
Timepoint
At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery
Method of measurement
Dyspnea index

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In this group, patients do not receive respiratory rehabilitation exercises before and after surgery.
Category
Other

2

Description
Intervention group: Patients in this group perform respiratory rehabilitation exercises only after surgery (moderate intensity interval training (MIIT)). The training of this group will include 5 minutes of warming up and 28 minutes of intermittent activity (4 minutes of activity with an intensity of 70% of maximum oxygen consumption and 3 minutes of activity with 30% of maximum oxygen consumption) and 5 minutes of cooling down.
Category
Rehabilitation

3

Description
Intervention group: In this group of patients, before and after surgery, they perform respiratory rehabilitation exercises (high intensity interval training (HIIT). The training of this group includes 5 minutes of warm-up and 28 minutes of intermittent activity (4 minutes of activity with an intensity of 85% maximum oxygen). consumption and 3 minutes of activity with 30% of maximum oxygen consumption) and 5 minutes of cooling.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Zargham Hosein Ahmadi
Street address
Masih Daneshvari Hospital, Daarabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
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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 Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohsen Abedi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Associate professor

Latest degree
Subspecialist

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Cardiac surgery

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Person responsible for updating data

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Name of organization / entity
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Position
Researcher

Latest degree
Master

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

Informed Consent Form
Undecided - It is not yet known if there will be 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