

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 rate, 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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Position
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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