

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison investigation of The role of threshold loading inspiratory muscle training, with and without biofeedback, on pulmonary function, functional capacity and quality of life in in-patient phase of coronary artery bypass graft, before and after surgery

Protocol summary

Study aim

comparison the effect of the threshold loading inspiratory muscle training , with and without respiratory biofeedback, on the respiratory and functional capacity of patients in the hospitalization phase, before and after coronary artery bypass graft surgery .

Design

A clinical trial with a control group, with parallel groups, a single blind , randomized by block method and stratification, on 50 patients.

Settings and conduct

Patients who are candidates for CABG surgery in the hospital, with informed consent of how interventions are performed in all groups, but without knowing how to group and with appropriate physical distance between groups, are entered into the study in a single blind manner. The first group performed 30 cycles of threshold inspiratory trainings at 30% load, with visual respiratory feedback and usual respiratory physiotherapy, twice a day, from the day before surgery until discharge. the second group, the intervention is similar to the first group, but without visual feedback, and in the control group, trainings are performed in the form of a placebo and with the usual physiotherapy.

Participants/Inclusion and exclusion criteria

Adult patients candidates for CABG surgery, between the ages of 50 and 80, in cardiac functional class 1 and 2, and without underlying respiratory disease and previous heart surgery, will be included in the study. Hemodynamic instability or the need for re-surgical intervention will cause the patient to exclude from the study.

Intervention groups

first intervention group: inspiratory trainings, with respiratory biofeedback and usual respiratory physiotherapy. second intervention group: Similar to the

first group and without respiratory biofeedback. Control group: inspiratory trainings in the form of placebo, with usual respiratory physiotherapy.

Main outcome variables

Inspiratory muscle strength; inspiratory flow; submaximal functional capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220801055596N1**

Registration date: **2022-10-25, 1401/08/03**

Registration timing: **prospective**

Last update: **2022-10-25, 1401/08/03**

Update count: **0**

Registration date

2022-10-25, 1401/08/03

Registrant information

Name

Bahareh Mehregan Far

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01
Expected recruitment end date
 2023-08-23, 1402/06/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison investigation of The role of threshold loading inspiratory muscle training, with and without biofeedback, on pulmonary function, functional capacity and quality of life in in-patient phase of coronary artery bypass graft, before and after surgery

Public title
 Comparison investigation of The role of threshold loading inspiratory muscle training, with and without biofeedback, on pulmonary function, in in-patient phase of coronary artery bypass graft, before and after surgery

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Adults of both sexes with coronary artery disease
 Patients aged between 50 and 80 years
 Patients are candidates for CABG surgery
 Absence of atrial fibrillation and stroke in the past
 Absence of heart surgery in the past
 Absence of advanced renal failure (CRF)
 Absence of chronic obstructive pulmonary disease (COPD)
 functional cardiac class (NYHA) 1 and 2
Exclusion criteria:
 Patients who do not understand the technique used
 Hemodynamic instability during tests or IMT training
 Emergency surgical intervention
 Mechanical ventilation time more than 24 hours
 Need to return to mechanical ventilation
 The need to return to surgical intervention
 The presence of symptoms at rest or with minimal effort
 Mobility disability
 The patient is blind or visually impaired
 Sternum infection or instability in the incision site
 Staying more than 4 days in the ICU
 Discharge the patient before completing the treatment period
 The patient's unwillingness to continue the research process
 The patient's inability to perform tests
 Presence of any malignancy and chemotherapy of the patient

Age
 From **50 years** old to **80 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this study, we have generally considered 3

intervention groups. And we use stratified and block method for randomization. At first, using the stratified technique and taking into account background factors including age (in two age groups, middle-aged and elderly), gender (male and female) and heart functional class (no symptoms and mild), in general 8 classes in is considered. Then, according to the volume of samples and in order to create a balance in the samples allocated to each of the studied groups, in each floor, we consider blocks of 3 people including 3 patients. And by using the random number table tool, we randomly assign each of the 3 patients to one of the groups. If the numbers were 1, 2, and 3, they would be assigned to group 1, if they were 4, 5, and 6, they would be assigned to group 2, and if they were 7, 8, and 9, they would be assigned to group 3.

Blinding (investigator's opinion)

Single blinded

Blinding description

The 3 treatment methods will be fully explained to the participants in this study, and they will also be informed that they will be assigned to one of these 3 groups, but about the way of randomization and allocation to groups, by The researcher and other health care workers do not find information. Then the intervention and evaluation is done in different groups in separate rooms, and when the samples are in the special section, the distance between the beds and the barrier between them is adjusted in such a way that it is impossible to exchange visual and auditory information, and how There is intervention between different groups for them. Also, the design of the intervention is such that in all three groups, the samples receive the desired intervention along with the usual treatment, which in the placebo group, the intervention is without creating a load and therefore ineffective.

Placebo

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

Building No. 2, 5th Floor, Shahid Beheshti University of Medical Sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway

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1985717443

Approval date
2022-05-15, 1401/02/25

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.058

Health conditions studied

1

Description of health condition studied

pulmonary complications after cardiac surgery,
functional capacity after cardiac surgery, inspiratory
muscle strength

ICD-10 code

J98.9

ICD-10 code description

Respiratory disorder, unspecified

Primary outcomes

1

Description

Dynamic inspiratory muscle strength

Timepoint

Before intervention beginning (pre-operation), 12 hours
after patient extubation (post-operation), before patient
discharge (post- operation)

Method of measurement

The score obtained using an electronic device for
measuring respiratory muscle strength and The amount
of lung volumes and with using the instructions of the
Association of Thoracic Surgeons, which is measured by
the stress index (S-index) and the unit of centimeters of
water (cmH2O).

2

Description

Peak inspiratory flow (PIF)

Timepoint

Before intervention beginning (pre-operation), 12 hours
after patient extubation (post-operation), before patient
discharge (post- operation)

Method of measurement

The score obtained using an electronic device for
measuring respiratory muscle strength and lung volumes
and with using the guidelines of the Association of
Thoracic Surgeons, for maximum inspiratory airflow in
one second and in unit of liters per second.

3

Description

Patient submaximal functional capacity

Timepoint

Before intervention beginning (pre-operation), before
patient discharge from hospital (post- operation)

Method of measurement

The distance traveled in meters in the walking test in 6

minutes (6MWT)

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention beginning (pre-operation), and two
weeks after patient discharge from hospital

Method of measurement

The score obtained using the questionnaire of the quality
of life of McNew cardiac patients, which has 27 items.

2

Description

The level of patient comfort during breathing training

Timepoint

Before intervention beginning (pre-operation), 12 hours
after patient extubation (post-operation), and before
patient discharge (post-operation)

Method of measurement

Using a 5-point scale and visualizing the patients level of
comfort while performing breathing trainings, from 1,
which is without difficulty , to 5, which is the inability to
perform the training.

3

Description

Hospital length of stay (HLOS)

Timepoint

Before the patient is discharged from the hospital

Method of measurement

The number of days the patient was hospitalized, from
the day of surgery to the day of discharge from the
hospital

Intervention groups

1

Description

The first intervention group: Inspiratory muscle training
with threshold loading (TL-IMT) with using an electronic
threshold loading device, at a load of 30% of the
maximum strength of the inspiratory muscles, twice a
day and 30 breathing cycles each time, and Along with
respiratory biofeedback, with using the visual feedback
in the monitor screen software. Also, patients receive the
usual respiratory physiotherapy, including breathing
exercises and deep breathing and coughing maneuvers
twice a day. All interventions start two days before the
operation and continue until the patient is discharged
from the hospital.

Category

Rehabilitation

2

Description

The second intervention group: inspiratory muscle breathing trainings with threshold loading (TL-IMT) using an electronic threshold loading device, at a load of 30% of the maximum inspiratory muscle strength, twice a day and 30 breathing cycles each time, and without biofeedback, is done. Also, the patients receive the usual respiratory physiotherapy including breathing exercises and deep breathing maneuvers and coughing twice a day. All interventions start two days before the operation and continue until the patient is discharged from the hospital.

Category

Rehabilitation

3

Description

Control group: Inspiratory muscle trainings are performed without threshold loading, but using a threshold loading device for inspiratory muscles and as a placebo, in such a way that the amount of load entered on the device is set to zero. Also, patients receive usual respiratory physiotherapy including breathing exercises and deep breathing and coughing maneuvers twice a day. All interventions start two days before the operation and continue until the patient is discharged from the hospital.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modares Educational and Therapeutic Hospital, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedigheh Sadat Naimi

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cardiac heart surgery ward, Shahid Modares educational and therapeutic hospital, Above Kaj Square, Saadat Abad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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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

Sedigheh Sadat Naimi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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