Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

Country
Iran (Islamic Republic of)

Phone
+98 21 2226 4827

Email address
b.mehreganfar@sbmu.ac.ir

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

Comparision 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 aftrer 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

City

Tehran

Province

Tehran

Postal code
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

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

City
Tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2207 4087

Fax
+98 21 2207 4101

Email
naimi.se@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Research and technology assistance, Shahid Beheshti University of medical sciences, Yaman St, Shahid Chamran highway,

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 9781

Fax
+98 21 2243 9981

Email
Zarghi@sbmu.ac.ir

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
Physiotherapy

Street address
Physiotherapy department, Rehabilitation Sciences Faculty, Shahid Beheshti University of Medical Science, In front of Bo Ali Hospital, Damavand St, Imam Hossein Sq,s,

City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7754 2057
Fax
+98 21 7759 1807
Email
naimi.se@sbmu.ac.ir

Person responsible for scientific 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
Physiotherapy
Street address
Physiotherapy department, Rehabilitation Sciences Faculty, Shahid Beheshti University of Medical Sciences, In front of Bo Ali Hospital, Damavand St, Imam Hossein Sq,
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7754 2057
Fax
+98 21 7759 1807
Email
naimi.se@sbmu.ac.ir

Person responsible for updating data

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
Physiotherapy
Street address
Physiotherapy department, Rehabilitation Sciences Faculty, Shahid Beheshti University of Medical Sciences, In front of Bo Ali Hospital, Damavand St, Imam Hossein Sq,
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7754 2057
Fax
+98 21 7759 1807
Email
naimi.se@sbmu.ac.ir

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