Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of preoperative segmental and diaphragmatic breathing exercise on functional mobility, length of hospital stay in on-pump versus off-pump coronary artery bypass graft patients.

Protocol summary

Study aim

To compare the effects of preoperative diaphragmatic and segmental breathing exercises on functional mobility, dyspnea and hospital length of stay in both on pump and off pump CABG.

Design

Prospective randomized clinical study with two groups interventional and control group enrolled between October 2023 to April 2024, followed for 6 months. Sample size of 170 and each group will contain 85 patients. The surgeon will be blind to procedure until he opens the envelope in preoperative room. The participants will be blind to the procedure both pre and postoperatively. The data analyzer will be blind till final statistical results calculation.

Settings and conduct

Integrated Medical Care & National hospital and Medical Centre Lahore Pakistan. Participant Blinding Researcher/Healthcare Provider Blinding Data Analyst Blinding

Participants/Inclusion and exclusion criteria

Inclusion Criteria Both male and female patients within the age of 40 to 70 years based upon coronary angiography, left ventricle ejection fraction ≥35% determined by echocardiogram will be included. Exclusion Criteria Patients with unstable angina, preoperative lung complication, on steroids and bronchodilators, with endocrine abnormalities such as hyper or hypothyroidism, neurological disability and/or musculoskeletal disorder, concomitant valve disease.

Intervention groups

Interventional group: Segmental & diaphragmatic breathing exercise is carried out on a lung segment with the aim of enhancing ventilation and oxygenation efficiency, promoting diaphragm movement. Control Group: Incentive spirometry helps to expand your lungs, strengthening your lungs and clearing mucus.

Main outcome variables

A Functional Mobility Scale (FMS) Dyspnea evaluation by using Modified medical research council dyspnea scale Pulmonary Complication evaluation by using Chest Xray Chest Expansion evaluation Dyspnea (D-12) Questionnaire

General information

Reason for update

I mistakenly mentioned wrong expected start and end date of recruitment. Now, I corrected both dates please approve this trial by this change.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230920059477N1**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-16, 1402/07/24**
Update count: **1**

Registration date

2023-10-14, 1402/07/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-10-22, 1402/07/30
Expected recruitment end date
2024-04-22, 1403/02/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of preoperative segmental and diaphragmatic breathing exercise on functional mobility, length of hospital stay in on-pump versus off-pump coronary artery bypass graft patients.

Public title
Effect of preoperative breathing exercises in coronary artery bypass graft patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both male and female patients within the age of 40 to 70 will be eligible. Patients will be included based upon clinical symptoms, coronary angiography, 12 lead ECG, echocardiogram and routine basic blood investigations which will be complete blood count. Patients will be included based upon renal function tests, liver function tests, clotting profile, hepatitis screening. Patients will be included based upon blood grouping and cross match, chest x-ray and left ventricle ejection fraction ≥35% determined by echocardiogram.
Exclusion criteria:
Emergent surgery due to unstable angina Hemodynamically unstable patients. Patients on preoperative inotropic support. Patients pericardial effusion and perioperative lung complication. Patient on steroids and bronchodilators. Patients with endocrine abnormalities such as hyper or hypothyroidism. Patients with neurological disability and/or musculoskeletal disorder. Concomitant valve disease. Patients having dysrhythmias or on permanent pacemaker and intra-aortic balloon pump. Anemic patient with hemoglobin less than 10 grams /dl. Pregnancy Obesity class II & III according to BMI >40kg/m2 Patients having Asthma, COPD and Interstitial Lung Disease
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized
Randomization description
After allocation of patients by card allocation method into control and experimental groups through randomization in surgeon clinic by the surgeon. There will be one box and patients' cards will be in sealed envelope with nothing written on envelope. Card will have patient hospital number and name. After completion of determined number of patients surgeon will pick half the number of envelope's without opening the envelope and will designate to group A and the other equal half to group B. The baseline data will be taken that will include functional mobility scale for mobility assessment, Modified medical research council dyspnea scale for dyspnea, pulmonary complications by using chest Xray, chest expansion evaluation and Dyspnea (D-12) Questionnaire for shortness of breath. Then both groups will receive breathing exercises as per defined criteria for 3 weeks. After the completion of treatment at 3 weeks the data regarding functional mobility scale for mobility assessment, Modified medical research council dyspnea scale for dyspnea, pulmonary complications by using chest Xray, chest expansion evaluation and Dyspnea (D-12) Questionnaire for shortness of breath will be taken for both groups of patients. It will be a prospective randomized clinical study where surgeon will be blind from on-pump and off-pump surgical procedure until he will open the envelope in preoperative room. The patient will be blind to the procedure both pre and postoperatively. And data analyzer will also be blind till getting the statistical results of techniques in both groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participant Blinding: The participants or patients undergoing the study would be kept unaware of certain key details. In this specific study, the patients might not be informed whether they are receiving "segmental" or "diaphragmatic" breathing exercises. They may also not know whether they are undergoing "on-pump" or "off-pump" coronary artery bypass graft surgery. This ensures that the patients' expectations and perceptions do not influence their responses or outcomes. Researcher/Healthcare Provider Blinding: The healthcare providers and researchers involved in the study would also be blinded to certain information. For example, the therapists or clinicians responsible for administering the breathing exercises should not be aware of whether they are providing "segmental" or "diaphragmatic" exercises to the patients. Similarly, the surgical team would not know whether they are performing an "on-pump" or "off-pump" procedure. Data Analyst Blinding: To maintain objectivity in data analysis, the individuals responsible for collecting and analyzing data would also be blinded to the treatment groups. In this case, the statisticians or data analysts should receive anonymized data without information about the specific treatment received by each patient. This prevents potential bias during the data analysis phase.
Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Lincoln University College

Street address

Lincoln university college-Medical campus,2, Jalan Stadium SS 7/15, SS7, 47301 Petaling Jaya, Selangor, Malaysia

City

Kuala Lumpur

Postal code

47301

Approval date

2023-09-21, 1402/06/30

Ethics committee reference number

LUC/RMC/06:10/2023A

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25.70

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description

Modified medical research council dyspnea scale

Timepoint

Baseline, preoperative after 2 weeks of treatment, postoperatively on day 1st, 2nd and before discharge from hospital.

Method of measurement

Chest expansion by flexi-curve, modified medical research council dyspnea scale for dyspnea evaluation, pulmonary complication evaluation by using Chest Xray, Dyspnea (D-12) Questionnaire for shortness of breath.

Secondary outcomes

1

Description

1. Functional mobility 2. Chest expansion 3. Dyspnea 4. pulmonary complications 5. length of hospital stay

Timepoint

Baseline, preoperatively after 2 weeks of treatment, postoperatively on day 1st, 2nd and before hospital discharge.

Method of measurement

Functional mobility scale, Chest expansion by flexi-curve, modified medical research council dyspnea scale for dyspnea evaluation, pulmonary complication evaluation by using Chest Xray, Dyspnea (D-12) Questionnaire for shortness of breath.

Intervention groups

1

Description

Intervention group: Segmental breathing exercise in which therapist will instruct the patients to inhale slowly through their nose, directing the air towards the target area. Physiotherapist will measure the expansion of that specific region through flexible curve as patient breathe in and out. Then therapist will give guide the patient to exhale slowly and completely through mouth, allowing the targeted area to relax. Diaphragmatic breathing exercise in which therapist will instruct the patient to start by taking a few slow, deep breaths through their nose. Guide the patient to inhale, physiotherapist will focus on expanding their abdomen, allowing it to rise and push their hand upward. Physiotherapist will guide the patients try to keep their chest relatively still during this phase. The patient will exhale slowly and completely through its mouth. As patient will exhale, therapist (WS) will measure patient’s abdomen falling and hand sinking back down through flexible curve. Ask the patient continue to breathe slowly and deeply in this manner, maintaining a relaxed and steady rhythm. Both techniques will be given to patients 2 sets once for 7days/week, (15 repetitions) for 15-20 minutes for 2 week preoperatively and postoperatively till discharged.

Category

Other

2

Description

Control group: Incentive spirometry is a medical device and a respiratory therapy technique used to help patients improve their lung function, particularly after surgery or when they are at risk of developing respiratory complications. It encourages deep breathing and sustained lung inflation to prevent atelectasis (lung collapse) and other pulmonary problems. Ask the patient to inhale as slowly and as deeply as patient can through the mouthpiece or facemask to raise the indicator to the predetermined target or as instructed by healthcare provider. Keep patients lips tightly sealed around the mouthpiece or maintain a snug fit with the facemask. After reached the target, hold his/her breath for about

3-5 seconds. This allows the air to reach the deeper parts of lungs and helps to open up the small air sacs (alveoli).Exhale slowly and completely through your mouth, emptying the lungs. Take a moment to rest and breathe normally for a few breaths. Perform this process for the prescribed number of breaths or as instructed by healthcare provider. Typically, patients are advised to do 5-10 repetitions every hour while awake for 1-2 weeks before operation.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Integrated Medical Care, National hospital and medical Centre Lahore Pakistan

Full name of responsible person
Professor Dr Zulfiqar Haider

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Hospital and medical Centre lahore Punjab

Full name of responsible person
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DHA Phase 1 Street 123 Lahore, Punjab

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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
National Hospital and medical Centre lahore Punjab

Proportion provided by this source
90

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
National Hospital and Medical Centre Lahore Punjab

Full name of responsible person
Zulfiqar Haider

Position
Professor

Latest degree
Medical doctor

Other areas of specialty/work
Cardiac Surgery

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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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Comparison of preoperative segmental and diaphragmatic breathing exercise on functional mobility, length of hospital stay in on-pump versus off-pump coronary artery bypass graft patients

When the data will become available and for how long
After collecting from patients

To whom data/document is available
After data collection from patients

Under which criteria data/document could be used
For study purpose only

From where data/document is obtainable
From hospitals

What processes are involved for a request to access data/document
A written informed consent from university hospital and patients will be taken.

Comments