

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq 35\%$  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

###### Name

Wajeeha Sahar

###### Name of organization / entity

Lincoln University College Malaysia

###### Country

Pakistan

###### Phone

+92 321 6094485

###### Email address

wajeehakarim31267@gmail.com

##### 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  $\geq 35\%$  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  $>40\text{kg/m}^2$  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

**Street address**

Sector L Dha phase 1, Lahore Punjab

**City**

Lahore

**Postal code**

54000

**Phone**

+92 322 9996000

**Email**

hzulfiqar35@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

National Hospital and medical Centre lahore Punjab

**Full name of responsible person**

Wajeaha Sahar, Zulfiqar Haider

**Street address**

DHA Phase 1 Street 123 Lahore, Punjab

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**Email**

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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

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

National Hospital and Medical Centre Lahore Punjab

**Full name of responsible person**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

National Hospital and Medical Centre Lahore Punjab

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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**