

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of incentive spirometry and deep breathing exercises on pulmonary functions after coronary artery bypass grafting

Protocol summary

Study aim

To compare the effects of incentive spirometry (IS) and deep breathing exercises (DBE) on pulmonary functions after coronary artery bypass grafting

Design

Pragmatic, community based, parallel-group, double-blind, randomised controlled trial

Settings and conduct

Conducted from July, 2019 - January, 2020 in Doctor's hospital Lahore Assesor was kept blind

Participants/Inclusion and exclusion criteria

CABG patients of either gender, aged between 35-60 years were selected by taking 20 in each group by convenient sampling. Patients with previous history of lung disorder, bone tuberculosis, osteoarthritis, neurological diseases and osteoporosis patients, chest operative and unstable hemodynamics patients were debarred.

Intervention groups

Group-A with 20 patients was handled with incentive spirometry only. Group-B comprised of 20 patients was treated with deep breathing exercises.

Main outcome variables

The outcome measures are values of oxygen saturation (SaO₂) by pulse oximetry, and partial pressures of oxygen (pO₂) and carbon dioxide (pCO₂) measured by arterial blood gases (ABGs).

General information

Reason for update

Acronym

EISDBEPFCABG

IRCT registration information

IRCT registration number: **IRCT20200204046373N2**

Registration date: **2021-10-20, 1400/07/28**

Registration timing: **retrospective**

Last update: **2021-10-20, 1400/07/28**

Update count: **0**

Registration date

2021-10-20, 1400/07/28

Registrant information

Name

Arooj Fatima

Name of organization / entity

The University Of Lahore

Country

Pakistan

Phone

+92 42 35414221

Email address

aruj43@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

2019-07-01, 1398/04/10

Actual recruitment end date

2020-01-05, 1398/10/15

Trial completion date

2020-01-05, 1398/10/15

Scientific title

Effects of incentive spirometry and deep breathing exercises on pulmonary functions after coronary artery bypass grafting

Public title

Physiotherapy techniques in post-CABG patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Post-CABG patients aged between 35-60 years Both gender

Exclusion criteria:

Patients with previous history of lung disorder bone tuberculosis osteoarthritis neurological diseases osteoporosis patients unstable hemodynamics

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was applied. Individual unit of randomization Parallel-group, concealed envelop method used Subjects were randomly allocated to both groups based on a computer-generated randomized design. The randomization allocation was sealed in opaque envelopes, and the clinical coordinator did not know about the group to which the subject would be assigned until the envelopes were opened.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessors and statisticians were blinded until the completion of the study. They were not aware of the interventions and groups. Concealed opaque envelopes were used for group assignment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board Committee

Street address

1 km, Bhotatyan chowk, Defence road

City

Lahore

Postal code

5400

Approval date

2019-06-01, 1398/03/11

Ethics committee reference number

IRB-UOL-FAHS/600/2019

Health conditions studied**1****Description of health condition studied**

Rotator cuff tendinopathy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

oxygen saturation (SaO₂)

Timepoint

Day 1 and day 4 after CABG surgery

Method of measurement

The outcome measures are values of oxygen saturation (SaO₂) by pulse oximetry

Secondary outcomes**1****Description**

oxygen saturation

Timepoint

Day 1 and day 4 after CABG surgery

Method of measurement

measured by pulse oximetry

Intervention groups**1****Description**

Intervention group: It received incentive spirometry in addition to routine physical therapy. Control group: It received deep breathing exercises along with routine physical therapy. About 2000 shockwaves of 0.32mJ/mm² per treatment were given as 10 sessions for the first six weeks (two sessions/week). The regions of tendinopathy were identified by the US, and the corresponding surfaces of the regions were marked. ESWT was conducted using a ShockMaster 500 device (GymnaUniphy NV, Bilzen, Belgium) twice a week for six weeks in total. Each treatment consisted of 2000 shocks with a frequency of 120 shocks per minute. Each ESWT session took about 15-20 minutes. ESWT application was performed on the supraspinatus, infraspinatus, teres minor, and subscapularis tendons. In successive treatments, an energy density of 0.32mJ/mm² was used. An isotonic gel was used as an intermediate before the probe was applied to the patient's shoulder, and no local anaesthetic was used.

Category

Rehabilitation

2**Description**

Control group: Routine treatment was administered to the patients in both experimental and RPT groups and it included these items: general exercise plan included ROM exercises, stretching, and strengthening exercises of abductors and flexors of the shoulder) performed twice a week in 10 sessions.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Doctor's Hospital Lahore

Full name of responsible person

Dr. Seema

Street address

1 km, Bhabatiyan chowk, Defence road

City

Lahore

Postal code

5400

Phone**Email**

aruj43@hotmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The University of Lahore

Full name of responsible person

Arooj Fatima

Street address

1 km, Bhabatiyan chowk, Defence road

City

Lahore

Postal code

5400

Phone

+92 42 35422636

Email

arooj.fatima1@uipt.uol.edu.pk

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The University of Lahore

Proportion provided by this source

100

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**

The University of Lahore

Full name of responsible person

Arooj Fatima

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

1 km, Bhabatiyan chowk, Defence road

City

Lahore

Province

Punjab

Postal code

5400

Phone

092 42 341 4391882

Email

arooj.fatima1@uipt.uol.edu.pk

Person responsible for scientific inquiries**Contact****Name of organization / entity**

The University of Lahore

Full name of responsible person

Arooj Fatima

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

1 km, Bhabatiyan chowk, Defence road

City

Lahore

Province

Punjab

Postal code

5400

Phone

092 42 341 4391882

Email

arooj.fatima1@uipt.uol.edu.pk

Person responsible for updating data

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Arooj Fatima

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

1 km, Bhabatiyan chowk, Defence road

City

Lahore

Province

Punjab

Postal code

5400

Phone

092 42 3414391882

Email

arooj.fatima1@uipt.uol.edu.pk

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
will be available on request

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data sets

When the data will become available and for how long

On request

To whom data/document is available

journals

Under which criteria data/document could be used

through mail

From where data/document is obtainable

From author, aruj43@hotmail.com

What processes are involved for a request to access data/document

Ask through email

Comments