Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Pakistan

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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, Bhobatiyan 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/mm2per 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 ESWTsession 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
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Sponsors / Funding sources

1

Sponsor
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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
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
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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