Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Effects of pre-operative physiotherapy on functional capacity, kinesiophobia and post operative ICU stay in subjects with Coronary artery disease (CAD) going for Coronary atrery bypass grafting (CABG)

Protocol summary

Study aim
The study aims to assess the level of kinesiophobia and find out the impact of pre-operative physiotherapy exercises on functional status of subjects suffering from coronary artery disease (CAD) going for coronary artery bypass grafting procedures.

Design
A concealed, randomized, double blinded, clinical trial with a parallel group design of 50 patients

Settings and conduct
Subjects who fulfill inclusion criteria will be enrolled and divided into two groups randomly by concealed envelope method. Blinding of care provider as well as outcome assessor will be maintained. The study will be conducted in physical therapy department of Kulsum International Hospital, Islamabad Pakistan. Study duration will be of 16 weeks.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Subjects with ejection fraction ≥ 25%, Exercise intensity of below anginal threshold, Subjects must be able to perform 6 minute walk test and would be able to tolerate mild to moderate activity level; Exclusion Criteria: Subjects with other systemic diseases or have undergone any surgical procedures previously

Intervention groups
Intervention group: Subjects will be provided inspiratory muscle training, breathing exercises and also chest clearance techniques. Three sessions will be given of 30-40 minutes each prior to their surgery. Inspiratory muscle training will be direct gentle resistance in inward and upward direction below xiphoid process during inspiration. To enhance thoracic expansion, incentive spirometer will also be used. Chest clearance will be done by active cycle of breathing technique (ACBT) and manual therapeutic chest percussion. Control Group: Subjects will be provided breathing exercises and also chest clearance techniques, 3 sessions of 30-40 minutes each

Main outcome variables
Functional capacity, Kinesiophobia, Cardiovascular and pulmonary endurance, ICU stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180417039344N2**
Registration date: **2019-10-11, 1398/07/19**
Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**
Update count: **0**

Registration date
2019-10-11, 1398/07/19

Registrant information

Name
Kiran Khushnood

Name of organization / entity
Shifa Tameer-e-Millat University

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-16, 1397/12/25

Expected recruitment end date
2019-09-29, 1398/07/07

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of pre-operative physiotherapy on functional capacity, kinesiophobia and post operative ICU stay in subjects with Coronary artery disease (CAD) going for Coronary atrery bypass grafting (CABG)

Public title
Effects of pre-operative physiotherapy on subjects going for CABG
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Ejection Fraction of ≥ 25% Exercise intensity of below anginal threshold Able to perform 6 minute walk test Able to tolerate mild to moderate activities
Exclusion criteria:
Individuals with other systemic diseases Previous surgical procedures Subjects with any neurological or cognitive impairment
Age
From **25 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects will be randomly divided into two groups by using concealed envelope method, in which there will be two envelopes. One envelope will contain a piece of paper with control group written on it, while the other will have experimental group written on the piece of paper enclosed in. First participant will choose one envelope and will hand it over to the investigator, the investigator will open the envelope and will allocate the participant into the group mentioned in the envelope (e.g. experimental group) without letting the participant know about which group he/ she will belong to. The next participant will be considered to be in the other group (control group). Then the third will come and choose the envelope, and the same process will be followed again till last participant.
Blinding (investigator's opinion)
Double blinded
Blinding description
There will be blinding of the care provider , they would not be informed about the participants of both groups. The outcome assessor will also be blinded regarding the type of intervention group the subject belongs to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee, Kulsum International Hospital
Street address
2020 Kulsum Plaza
City
Islamabad
Postal code
44000
Approval date
2019-03-08, 1397/12/17
Ethics committee reference number
KIH-EC-PT-009

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease
ICD-10 code
I25
ICD-10 code description
Chronic ischemic heart disease

Primary outcomes

1

Description
Functional capacity
Timepoint
At baseline before physiotherapy session, then after 3 physiotherapy sessions, and again after surgical procedure.
Method of measurement
By 6 minute walk test

2

Description
Kinesiophobia
Timepoint
At baseline before physiotherapy session, then after 3 physiotherapy sessions, and again after surgical procedure.

Method of measurement
Tampa scale of Kinesiophobia for heart

3

Description
Cardiovascular and pulmonary endurance
Timepoint
At baseline before physiotherapy session, then after 3 physiotherapy sessions, and again after surgical procedure.
Method of measurement
VO2 max and BORG scale

Secondary outcomes

1

Description
Stay in ICU
Timepoint
After surgical procedure in ICU
Method of measurement
By measuring number of days a subject stays in ICU after surgical procedure

Intervention groups

1

Description
Intervention group: Subjects will be provided inspiratory muscle training, breathing exercises and also chest clearance techniques. Three sessions will be given of 30-40 minutes each prior to their surgery. Inspiratory muscle training will be direct gentle resistance in inward and upward direction below xiphoid process during inspiration. To enhance thoracic expansion, incentive spirometer will also be used. Chest clearance will be done by active cycle of breathing technique (ACBT) and manual therapeutic chest percussion.
Category
Rehabilitation

2

Description
Control Group: Subjects will be provided breathing exercises and also chest clearance techniques, 3 sessions of 30-40 minutes each
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical therapy deprtment, Kulsum International Hospital
Full name of responsible person
Riafat Mehmood
Street address
2020 Kulsum Plaza
City
Islamabad
Postal code
44000
Phone
+92 51 8446666
Email
riafat.turabi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kulsum International Hospital
Full name of responsible person
Riafat Mehmood
Street address
2020 Kulsum Plaza, Blue Area
City
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Postal code
44000
Phone
+92 51 8446666
Email
riafat.turabi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kulsum International Hospital
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
Sponsor: country of origin
Country of origin
PK
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shifa Tameer-e-Millat University
Full name of responsible person
Kiran Khushnood
Position
Lecturer
Latest degree
Master

Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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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
Yes - There is a plan to make this available
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
Personal details would not be shared, although data related to study, outcomes and procedures will be shared.
When the data will become available and for how long
August 2019
To whom data/document is available
All the professionals working in clinical settings or in academia, undergraduate and post graduate students in the relevant field
Under which criteria data/document could be used
Data would be shared for use for betterment of patients, and requests will be reviewed by investigators of the study
From where data/document is obtainable
Via email to kiran_dpt.ahs@stmu.edu.pk
What processes are involved for a request to access data/document
kiran_dpt.ahs@stmu.edu.pk An email with data sharing request to the mentioned mailing address will lead to sharing of data regarding the study
Comments