# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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

**Country**
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
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**Postal code**
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**Phone**
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**Email**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kulsum International Hospital
**Full name of responsible person**
Riafat Mehmood
**Street address**
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**Postal code**
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**Phone**
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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**
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
**Street address**
Dar-ul-Shifa Campus, Street 3, H8/1
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## Person responsible for scientific inquiries

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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**