Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of preoperative Respiratory Muscle Training for improvement of postoperative Health Related Quality of Life in Mitral Valve Replacement patients”

Protocol summary

Study aim
To evaluate comparative effectiveness of preoperative Respiratory Muscle Training versus conventional treatment for improvement of postoperative Health Related Quality of Life in Mitral Valve Repair/Replacement patients.

Design
Single Blinded Quasi Experimental Clinical Design

Settings and conduct
Faisalabad Institute of Cardiology, Faisalabad, Punjab, Pakistan. This setting is used to conduct the research. Participants will be allocated in groups to fulfil the inclusion criteria and those who are in exclusion criteria will be excluded. Participants will be assessed on the basis of HHQ-GP-1 as a screening tool. Participants will be assessed on basis of EuroQol-5-D-5L and NYHA classification system. Trials will be performed and results will be noted at baseline, 3rd week and postoperative before discharge.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Both male and female patients will be included. Age 25-50 years. Patients who are awaiting mitral valve repair/replacement. Exclusion Criteria: Patients with any other significant valvar or coronary artery diseases necessitating surgical intervention. Patients who have chronic respiratory conditions. Patients who have neurological deficits. Patients who are morbid obese according to Body Mass Index. Patients who reveal inconsistency with exercise protocol. Patients with chronic renal insufficiency.

Intervention groups
Treatment will be provided for 2 times, 10-15 repetitions, five days and three weeks to both groups. Respiratory Muscle Training group will perform segmental breathing, huff-coughing breathing and incentive spirometer breathing exercises and Conventional Muscle Training will perform deep breathing and diaphragmatic breathing exercises with pursing of lips.

Main outcome variables
Health Related Quality Of Life Euro-Qol 5D-5L, New York Heart Association Classification (NYHA).

General information

Reason for update
Typing Error

Acronym

IRCT registration information
IRCT registration number: **IRCT20220704055364N1**
Registration date: **2022-09-23, 1401/07/01**
Registration timing: **prospective**

Last update: **2023-01-30, 1401/11/10**
Update count: **3**

Registration date
2022-09-23, 1401/07/01

Registrant information

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Name of organization / entity
Faisal institute of health sciences faisalabad

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-04, 1401/11/15

Expected recruitment end date

2023-05-06, 1402/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of preoperative Respiratory Muscle Training for improvement of postoperative Health Related Quality of Life in Mitral Valve Replacement patients”

Public title

Effects of preoperative Respiratory Muscle Training for improvement of postoperative Health Related Quality of Life in Mitral Valve Replacement patients”

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both male and female patients will be included. Age 25-50 years. Patients who are awaiting mitral valve repair/replacement.

Exclusion criteria:

Patients with any other significant valvar or coronary artery diseases necessitating surgical intervention. Patients who have chronic respiratory conditions. Patients who have neurological deficits. Patients who are morbid obese according to Body Mass Index. Patients who reveal inconsistency with exercise protocol. Patients with chronic renal insufficiency.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **20**

patients will be non-randomly assigned each group will comprise of 20 patients

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Government College university Faisalabad

Street address

C389+CXH, Kotwali Rd, Gurunanakpura, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Approval date

2022-05-09, 1401/02/19

Ethics committee reference number

GCUF/ERC/1026

Health conditions studied

1

Description of health condition studied

Mitral valve Replacement is used to treat the diseased mitral valve.

ICD-10 code

02RG38Z

ICD-10 code description

Mitral valve Replacement

Primary outcomes

1

Description

The EuroQol-5 D-5L (EQ-5D-5L), is a most widely used generic tool to measure the health-related quality of life (HRQoL) and considered suitable for patients with pulmonary problems.

Timepoint

3time points including Baseline, After 3rd week, and postoperatively before discharge.

Method of measurement

EuroQol-5D-5L will be measured by EuroQol-5D-5L Questionnaire

Secondary outcomes

1

Description

The New York Heart Association classification is a straight forward system use for determining heart failure. It divides patients into four Classes: Class I can complete any activity requiring ≤ 7 Metabolic Equivalent, Class II can complete any activity requiring ≤ 5 Metabolic Equivalent, Class III can complete any activity requiring ≤ 2 Metabolic Equivalent ,Class IV cannot do or cannot complete any activity requiring at least less than ≥ 2

Metabolic Equivalent ,depending upon their limits during physical activity; these limitations/symptoms include normal breathing, varying degrees of shortness of breath and angina discomfort

Timepoint

3 time points including Baseline, After 3rd week, and postoperatively before discharge

Method of measurement

NYHA Classification (Newyork Heart Association Classification) will be measured by NYHA grading system

2

Description

Postoperative Duration of Mechanical Ventilation (hours) use was defined from the time the patient entered the ICU to the moment of extubation

Timepoint

1 time postoperatively

Method of measurement

Postoperative Duration of Mechanical Ventilation will be measured in hours from patient entered the ICU to the moment of extubation

3

Description

Postoperative Hospital Stay (Days) is the lenght of days patient stay in hospital after surgery

Timepoint

1 time postoperatively

Method of measurement

Postoperative Hospital Stay (Days) will be measured from patient stay in hospital after surgery

Intervention groups

1

Description

Intervention group 1;Respiratory muscle training consisting of Segmental Breathing Exercise, huff-coughing techniques and instructions of flow-IS-based Incentive Spirometer, 10-15 repetitions for five days and three weeks.

Category

Rehabilitation

2

Description

Control group: ,Breathing exercises consisting of 10 deep breathing attempts, diaphragmatic breathing and pursing of the lip, 10-15 repetitions for five days and three weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faisalabad Institute of Cardiology Faisalabad

Full name of responsible person

Amir Mushtaq

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Self Financed

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Faisal Institute of Health Sciences

Full name of responsible person
Dr Umama Umar

Position
Principal Investigator /Student

Latest degree
Medical doctor

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable