

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Name

Umama Umar

##### Name of organization / entity

Faisal institute of health sciences faisalabad

##### Country

Pakistan

##### Phone

+92 317 7816746

##### Email address

umamaumar450@gmail.com

##### 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  $\leq 7$  Metabolic Equivalent, Class II can complete any activity requiring  $\leq 5$  Metabolic Equivalent, Class III can complete any activity requiring  $\leq 2$  Metabolic Equivalent ,Class IV cannot do or cannot complete any activity requiring at least less than  $\geq 2$

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

##### **Street address**

Faisalabad Institute of Cardiology, Club-Road, Opposite Chenab Club Faisalabad

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ms.ic.fsd@punjab.gov.pk

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Faisal Institute of Health Sciences Faisalabad.

##### **Full name of responsible person**

Komal Tariq

##### **Street address**

673-A, Canal Road E, A Block Peoples colony, Faisal Hospital, Faisalabad

##### **City**

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38000

##### **Phone**

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##### **Email**

fihsfsd@outlook.com

#### **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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## Person responsible for scientific inquiries

### Contact

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**Position**

Lecturer

**Latest degree**

Master

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Physiotherapy

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## Person responsible for updating data

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**Latest degree**

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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