

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of incentive spirometry and peak expiratory flow meter to evaluate cardiorespiratory parameters after valvular surgery

#### Protocol summary

##### Study aim

The purpose of this study is to compare incentive spirometry and peak expiratory flow meters to evaluate the cardiorespiratory parameter following valvular surgery and determine which has a better impact on cardiopulmonary problems after valvular surgery experience

##### Design

A concealed, randomized, single blinded study with two group/parallel design of 60 patients enrolled. And then allocated their respective groups. The treatment duration will be about 3 weeks.

##### Settings and conduct

Data will be collected from ICU of Ch. Pervaiz Elahi Institute of Cardiology Hospital, Multan

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Both male and female Patients with age ranges of (35-65) Patients who had recently undergone extubated heart valve surgery and who will be able to comply with the instructions and sign the consent form. Patients who undergone median sternotomy-based valvular surgery. Patients with stable hemodynamics  
Exclusion criteria Patients who needed to be intubated for more than 48 hours following surgery. Re-intubation throughout the healing process. Patients who within the previous three months had a history of a respiratory infection. Patients undergo CABAG surgery. Patients with any neuromuscular disease, renal disease, smokers, alcohol, anemia, and pregnant females.

##### Intervention groups

The total patient population will be split into two groups, one of which will use a peak expiratory flow meter and the other incentive spirometry

##### Main outcome variables

Cardiorespiratory parameters Blood Pressure Heart rate Oxygen saturation Respiratory rate ABGs (Atrial Blood Gasses)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230123057185N1**

Registration date: **2023-03-17, 1401/12/26**

Registration timing: **prospective**

Last update: **2023-03-17, 1401/12/26**

Update count: **0**

##### Registration date

2023-03-17, 1401/12/26

##### Registrant information

##### Name

kashaf khan Anjum bhutta

##### Name of organization / entity

Muhammad Institute of Medical and Allied Sciences, Multan

##### Country

Pakistan

##### Phone

+92 301 6968008

##### Email address

kashafbhatta1@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-24, 1402/01/04

##### Expected recruitment end date

2023-04-28, 1402/02/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of incentive spirometry and peak expiratory flow meter to evaluate cardiorespiratory parameters after valvular surgery

**Public title**

Comparison of incentive spirometry and peak expiratory flow meter to evaluate cardiorespiratory parameters after valvular surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients of both sexes i-e male and female Patients with age ranges of (35-65yrs.) Patients who have recently undergone extubated heart valve surgery and who will be able to comply with the instructions and sign the consent form. Patients who underwent median sternotomy-based valvular surgery. Patients with stable hemodynamics

**Exclusion criteria:**

Patients who needed to be intubated for more than 48 hours following surgery. Re-intubation throughout the healing process Patients who within the previous three months had a history of a respiratory infection Patients undergo CABG surgery. Patients with any neuromuscular disease, renal disease, smokers, alcohol, anemia, and pregnant females.

**Age**

From **35 years** old to **65 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization is simple. Total participants will be divided into two groups by lottery method. Each member of the population will be assigned by a number, after which members will be selected at random into groups. allocation concealment will also carried out.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The allocation will be known to the patients, the doctor, and the data analyst. However, the interventionist's therapist will be kept unaware. The trial follows established protocols to keep the staff members who delivered the interventions apart from those who took part in other aspects of the trial. the interventional personnel will be maintained masked to outcomes measurements and trial data and to minimize the biasness.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Muhammad Institute of Medical and Allied Sciences  
Multan

**Street address**

near sabzazar metro station Multan

**City**

Multan

**Postal code**

66000

**Approval date**

2022-12-16, 1401/09/25

**Ethics committee reference number**

MIMAS/02/23/Farah

**Health conditions studied****1****Description of health condition studied**

Heart valvular surgery

**ICD-10 code**

Y83.1

**ICD-10 code description**

Aortic regurgitation, Aortic stenosis, Mitral stenosis, Mitral regurgitation, Marfan's syndrome, Rheumatic fever, Endocarditis, Atresia, Heart valve disease, Valvular heart disease, Valvular surgery

**Primary outcomes****1****Description**

Blood Pressure

**Timepoint**

Before interventions and after 3 weeks of interventions

**Method of measurement**

Cardiorespiratory parameters like blood pressure will be measured by Arterial line.

**2****Description**

Heart rate

**Timepoint**

Before interventions and after 3 weeks of interventions

**Method of measurement**

Cardiorespiratory parameters like heart rate will be measured by arterial line.

### 3

#### **Description**

Respiratory rate

#### **Timepoint**

Before interventions and after 3 weeks of interventions

#### **Method of measurement**

Cardiorespiratory parameters like respiratory rate will be measured by arterial line.

### 4

#### **Description**

ABG's ( Atrial blood gasses)

#### **Timepoint**

Before interventions and after 3 weeks of interventions

#### **Method of measurement**

Cardiorespiratory parameters like ABG's (atrial blood gasses) will be measured by arterial line.

### 5

#### **Description**

Oxygen saturation

#### **Timepoint**

Before interventions and after 3 weeks of interventions.

#### **Method of measurement**

Oxygen saturation will be measured by probe of pulse oximeter.

## **Secondary outcomes**

### 1

#### **Description**

Rating of perceived exertion

#### **Timepoint**

Before intervention and 3 weeks after intervention

#### **Method of measurement**

Rate of perceived exertion will be measured by Borg scale

### 2

#### **Description**

SF8 quality of life (A questionnaire)

#### **Timepoint**

Before intervention and 3 weeks after intervention

#### **Method of measurement**

patients will fill the SF8 quality of life questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Incentive spirometry 1.The patient will be asked to lie flat on a bed or a chair. The patient will be asked to grasp a pillow to help corset or brace the incision to lessen the pain on chest. 2.The patients will also be instructed to place the mouthpiece in their mouth and seal their lips tightly around it before slowly and fully exhaling.3.The next step is to inhale via their mouth

slowly and deeply. The ball will rise when the breath will be taken.4.Patient will be asked to try to get the ball as high as possible.5.The patient will be instructed to hold their breath for at least 10 seconds after receiving it.6.After that, he or she will slowly exhale through their mouth. Next, they will be asked to take a 30 to 60 second break.7 It will be repeated 10 times for 3 sets for 3 weeks.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group 2: Peak expiratory flow meter 1.Patient will be asked to stand or sit up straight. 2.It will be made sure the red marker is located at the meter's base. 3.The patient will inhale deeply until their lungs are filled .4.The participant will put the mouthpiece in his/her mouth and then press their lips firmly against the mouthpiece of the peak flow meter. 5.Then he/she will expel all the air as quickly and forcefully as they can. 6.On the meter, the number next to the red marker will be noted. 7. Pressure will be continually turned up.8. Maximal expiratory pressure would be found at that point, and this is where training of patient will be started. The knob will be turned back to one, and then it will be fully turned to the left. 9.While training, patient will be asked to rest for a minimum of 15 to 20 seconds.10.One set is made up of 3 repetitions of this exercise. 11. 15 training breaths across 3 breath sets will be completed.12. Intervention will be done in 3 weeks.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

ICU of Ch. Pervaiz Elahi Institute of Cardiology hospital, Multan.

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

Dr. Atiq-ul-Mannan

##### **Street address**

Peera ghaeeb road Chock kumhara wala Multan

##### **City**

Multan

##### **Postal code**

66000

##### **Phone**

+92 334 6036848

##### **Email**

atiqulmannan23@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Ch. Pervaiz Elahi Institute of Cardiology Hospital,  
Multan

**Full name of responsible person**

Dr. Atiq-ul-Mannan

**Street address**

Tariq road Multan

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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**

Ch. Pervaiz Elahi Institute of Cardiology Hospital, Multan

**Proportion provided by this source**

50

**Public or private sector**

Public

**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**

Muhammad Institute of medical and Allied sciences  
Multan

**Full name of responsible person**

Dr. Farah Zahid

**Position**

lecturer

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiopulmonary Physical Therapy

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**Province**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ch. Pervaiz Elahi Institute of Cardiology Hospital,  
Multan

**Full name of responsible person**

Dr. Atiq-ul-Mannan

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

FCPS Pulmonology

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atiqulmannan23@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Muhammad Institute of medical and allied sciences  
Multan

**Full name of responsible person**

Kashaf Khan Anjum Bhutta

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physical Therapy

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house no. 86A/177, street no. 11 Mohalla Ameerabad  
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**Province**

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**Postal code**

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kashafbhatta1@gmail.com

## 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**

Confidentiality of individual personal information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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**

Primary outcomes measures data will be shared

**When the data will become available and for how long**

after 6 months

**To whom data/document is available**

General population

**Under which criteria data/document could be used**

For Rehabilitation purposes

**From where data/document is obtainable**

From Google Scholar

**What processes are involved for a request to access data/document**

Emails

**Comments**