Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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

kashafbhutta1@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
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+92 334 6036848
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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

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Tariq road Multan

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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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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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Person responsible for updating data

Contact

Name of organization / entity
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Position
student

Latest degree
Bachelor

Other areas of specialty/work
Physical Therapy

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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