

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Effects of Acapella and Positive End Expiratory Pressure Device among Patients with Laparoscopic Surgery

Protocol summary

Study aim

To find the effects of Acapella and positive end expiratory pressure device on pulmonary function test, cough maneuver, sputum diary and dyspnea in post-operative laparoscopic patients.

Design

Two parallel group , Double blinded, randomized clinical trial with pre and post assessment

Settings and conduct

Surgical Ward/Intensive Care Unit Services Hospital Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age criteria of 35-55yrs Patients undergone Laparoscopic Surgery (Cholecystectomy, Liver Biopsy, Ectopic Pregnancy, Splenectomy, and Ovarioectomy). Both male and female Exclusion Criteria: Patients body mass index < 15 kg.m-2 or > 30 kg.m-2 Patient's history of respiratory tract infection within three months Patient's baseline arterial partial pressure of oxygen (PaO2) < 70 mmHg or arterial partial pressure of carbon dioxide (PaCO2) > 50 mmHg; baseline forced expiratory volume in 1 s (FEV1) < 30% of predicted.

Intervention groups

Laparoscopic Surgery Patients using Acapella and Positive End Expiratory Pressure Device.

Main outcome variables

Dyspnea will be checked by Multidimensional Dyspnea Profile (MDP) Sputum Diary will be checked by Breathlessness, Cough, Sputum Scale (BCSS) Pulmonary Function Test will be checked by Spirometer and following four readings will be taken FVC, FEV1, FVC/FEV1, PEFR

General information

Reason for update

Acronym

CEAPEPPLS

IRCT registration information

IRCT registration number: **IRCT20191117045462N9**

Registration date: **2023-11-08, 1402/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Wajeeha Zia

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 42 35126110

Email address

wajeeha_z@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2024-01-31, 1402/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effects of Acapella and Positive End Expiratory Pressure Device among Patients with Laparoscopic Surgery

Public title

Comparative Effects of Acapella and Positive End Expiratory Pressure Device among Patients with Laparoscopic Surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age criteria of 35-55yrs Patients undergone Laparoscopic Surgery (Cholecystectomy, Liver Biopsy, Ectopic Pregnancy, Splenectomy, and Ovarioectomy) Both male and female

Exclusion criteria:

Patients body mass index < 15 kg.m-2 or > 30 kg.m-2
Patient's history of respiratory tract infection within three months
Patient's baseline arterial partial pressure of oxygen (PaO2) < 70 mmHg or arterial partial pressure of carbon dioxide (PaCO2) > 50 mmHg; baseline forced expiratory volume in 1 s (FEV1) < 30% of predicted.

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be recruited by Convenient sampling technique and then then patients will be divided into two groups by simple random sampling through sealed opaque enveloped.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants and outcome assessor will be blind. Assessment will be done by another therapist who will not be involved in treatment and data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Riphah college of rehabilitation & Allied Health

Sciences

Street address

25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore.

City

Lahore

Postal code

5400

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

REC/RCR & AHS/23/0328

Health conditions studied

1

Description of health condition studied

Cholecystectomy

ICD-10 code

Z90.4

ICD-10 code description

Acquired absence of other specified parts of digestive tract

2

Description of health condition studied

Splenectomy

ICD-10 code

D73.0

ICD-10 code description

Hyposplenism

Primary outcomes

1

Description

Dyspnea

Timepoint

Pre post treatment

Method of measurement

will be checked by Multidimensional Dyspnea Profile (MDP)

2

Description

Sputum Diary

Timepoint

pre post treatment

Method of measurement

Breathlessness, Cough, Sputum Scale (BCSS)

3

Description

Pulmonary Function Test

Timepoint

pre post treatment

Method of measurement

portable spirometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Laparoscopic Surgery patients using Acapella

Category

Treatment - Devices

2

Description

Intervention group: Laparoscopic Surgery patients using Positive End Expiratory Pressure Device

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Riphah college of rehabilitation & Allied Health Sciences

Full name of responsible person

Riphah college of rehabilitation & Allied Health Sciences

Street address

25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore.

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kareenakhan107@gmail.com

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<https://www.riphah.edu.pk>

2

Recruitment center

Name of recruitment center

Riphah college of rehabilitation & Allied Health Sciences

Full name of responsible person

Kareena Imran

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Web page address

<https://www.riphah.edu.pk>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Wajeeha

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wajeeha_z@yahoo.com

Grant name

Educational

Grant code / Reference number

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

No

Title of funding source

Riphah International University

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University

Full name of responsible person

Kareena Imran

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Wajeeha

Position

Assistant Professor

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Student

Latest degree

Master

Other areas of specialty/work

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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

There is no further information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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