Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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2

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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 updating data

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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