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Perioperative respiratory therapy hierarchical management in enhanced recovery after surgery

Submission date 12/05/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/05/2025	**Overall study status** Completed	
Last Edited 27/05/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
This study focuses on improving recovery after surgery, especially for patients having chest or upper abdominal operations. After surgery, some patients develop breathing problems like lung infections or difficulty getting enough oxygen, which can slow recovery and increase hospital stays. The study tests a new approach called "graded respiratory care management," which includes breathing exercises before surgery, special lung-protecting techniques during surgery and guided breathing exercises after surgery. This study aims to see if this approach helps patients recover faster, reduces breathing problems, and shortens hospital stays.

Who can participate?
Adults (18 years or older) scheduled for chest or upper abdominal surgery can join.

What does the study involve?
Participants are randomly divided into two groups:
1. Standard care group: Receives usual medical treatment.
2. Graded respiratory care group: Receives extra breathing exercises before surgery, lung-protecting techniques during surgery, and guided exercises after surgery.

Doctors will check lung function (using simple breathing tests), blood oxygen levels, and track recovery progress.

What are the possible benefits and risks of participating?
Possible benefits:
- Better lung recovery after surgery.
- Lower chance of breathing problems.
- Possibly shorter hospital stay.

Possible risks:
- Breathing exercises may feel tiring.
- Minor discomfort from tests (e.g., blood draws).
- No extra physical harm—all methods are safe and proven.

Where is the study run from?
The Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, China

When is the study starting and how long is it expected to run for?
January 2022 to June 2025

Who is funding the study?
This study receives no external funding.

Who is the main contact?
Dr. Ge Huiqing, Gehq@zju.edu.cn

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2022021530

Study information

Scientific Title
Respiratory stratification for periorperative optimization in enhanced recovery after surgery: a multicenter study

Acronym
RESPRO-ERAS

Study objectives
Graded perioperative respiratory management reduces length of stay

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 15/02/2022, Ethics Committee of Sir Run Run Shaw Hospital Zhejiang University School of Medicine (3 East Qinchun Rd, Sir Run Run Shaw Hospital, Hangzhou, 310016, China; +86 571 86006811; 594961420@qq.com), ref: 20250323

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact detail to request a participant information sheet.

Health condition(s) or problem(s) studied
Recovery after surgery

Interventions
Participants are randomized using a simple randomization method at the time of recruitment into an intervention group and a control group.

Four aspects of the patient's condition were assessed: aerosol therapy, bronchial hygiene, lung expansion, and aerobic exercise.

-Control Group
Guided deep breathing exercises, to achieve the pre-operative assessment's FVC (forced vital capacity)

-Experimental Group
1. Aerosol Therapy AT
Score 0-2: Continue previous treatment
Score 3-4: Bronchodilator inhalation (Salbutamol 2.5 mg, three times daily)
Score 5-6: Bronchodilator inhalation (Salbutamol 2.5 mg + Ipratropium Bromide 0.5 mg, three times daily)
Score >7: Bronchodilator inhalation (Salbutamol 2.5 mg + Ipratropium Bromide 0.5 mg, three times daily) + combination therapy, three times daily

2. Bronchial Hygiene (BH)
Score 0-2: Deep breathing, 3-5 times per hour
Score 3-4: Coughing guidance 3-5 times per hour + Flutter 3-5 times per hour for 6-8 hours
Score 5-6: Metaneb or High Frequency Chest Wall Oscillation twice daily
Score >7: Same as 5-6, with possible bronchoscopy if necessary

3. Lung Expansion (LE)
Score 3-4: Inhalation device (IS) 5-10 times per hour for 6-8 hours
Score >5: If ineffective, PEP (Positive Expiratory Pressure) with a three-ball resistance device, set to maximum resistance
FVC < 15 ml/kg: Non-invasive ventilation 12/6 cmH2O for 2 hours twice daily

4. Aerobic Exercise (AE)
Daily walking distance and time: 6-minute walk distance / 6 * 20 minutes * 0.8 meter

Intervention Type
Procedure/Surgery

Primary outcome measure
Length of stay measured using data collected from the hospital record at one time point

Secondary outcome measures
Maximum Inspiratory Pressure and Forced Vital Capacity, measured using pulmonary function testing, post-operatively at day 2

Overall study start date
01/01/2022

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Peri-operative patient
2. Age over 18 years old

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria

1. Age less than 18 years old
2. Pregnant
3. Neuromuscular disease
4. Other systemic diseases induced ineligibility for surgery
5. Impaired cognitive functions
6.Refuse to enroll

Date of first enrolment
15/02/2022

Date of final enrolment
05/06/2025

Locations

Countries of recruitment
China

Study participating centre
Sir Run Run Shaw Hospital, Zhejiang University, School of Medicine
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Hangzhou
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Study participating centre
Yongkang First People's Hospital
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Study participating centre
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Study participating centre
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No. 1, Wanlongcheng South Gate Street, Shuxi Subdistrict
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Study participating centre
Zhejiang Putuo Hospital
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316199

Study participating centre
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Study participating centre
Jiaxing First Hospital
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Study participating centre
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Study participating centre

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Study participating centre
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Sponsor type
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ROR
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available