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Perioperative respiratory therapy hierarchical management in enhanced recovery after surgery

Submission date
12/05/2025

Recruitment status
No longer recruiting

Registration date
16/05/2025

Overall study status
Completed

Last Edited
17/09/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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?
All control group participants were enrolled in one period, and all treatment group participants were enrolled in a later, separate period:
1. Standard care group (control): Receives usual medical treatment.
2. Graded respiratory care group (treatment): 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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 non-randomized intervention trial with a non-concurrent enrollment design

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions:
This study is now a non-randomized intervention trial with a non-concurrent enrollment design, with control group participants enrolled in one period, and all treatment group participants enrolled in a later, separate period.

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

Previous 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.

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Intervention Type
Procedure/Surgery

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

Key secondary outcome(s))
Maximum Inspiratory Pressure and Forced Vital Capacity, measured using pulmonary function testing, post-operatively at day 2

Completion date
30/06/2025

Eligibility

Key inclusion criteria

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

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
3 East Qinchun Rd, Sir Run Run Shaw Hospital
Hangzhou
China
310016

Study participating centre
Yongkang First People's Hospital
No. 599, Jinshan West Road
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321399

Study participating centre
Shaoxing People's Hospital
No. 123, Baiyutan Road, Yuecheng District
Shaoxing
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312035

Study participating centre
Wuyi County First People's Hospital
No. 1, Wanlongcheng South Gate Street, Shuxi Subdistrict
Jinhua
China
321299

Study participating centre
Zhejiang Putuo Hospital
No. 19, Wenkang Street, Donggang Subdistrict, Putuo District
Zhoushan
China
316199

Study participating centre
Lanxi People's Hospital
No. 896, Huancheng West Road
Lanxi
China
321102

Study participating centre
Jiaxing First Hospital
No. 1882, Zhonghuan South Road
Jiaxing
China
314001

Study participating centre
Ningbo Yinzhou No. 2 Hospital
No. 998, Qianhe North Road
Ningbo
China
315192

Study participating centre
The First Affiliated Hospital of Wenzhou Medical University
No. 2, Fuxue Lane
Wenzhou
China
325000

Study participating centre
Ningbo No. 1 Hospital
No. 59, Liuting Street
Ningbo
China
315010

Study participating centre
Taizhou Hospital
150, Ximen Street
Linhai
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Sponsor information

Organisation
Sir Run Run Shaw Hospital

ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes