

Perioperative respiratory therapy hierarchical management in enhanced recovery after surgery

Submission date 12/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/09/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

Dr Huiqing Ge

ORCID ID

<https://orcid.org/0000-0002-5822-2998>

Contact details

Sir Run Run Shaw Hospital

3 East Qinchun Rd

Hangzhou

China

310016

+86 13588706787

gehq@zju.edu.cn

Type(s)

Scientific

Contact name

Miss Yiqing Xu

ORCID ID

<https://orcid.org/0000-0002-4730-9633>

Contact details

Sir Run Run Shaw Hospital

3 East Qinchun Rd

Hangzhou

China

310016
+86 13634115344
xuyiqing@srrsh.com

Type(s)

Public

Contact name

Mr Runze He

Contact details

Sir Run Run Shaw Hospital
3 East Qinchun Rd
Hangzhou
China
310016
+86 19883130216
2259784284@qq.com

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 perioperative 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
Yongkang
China
321399

Study participating centre
Shaoxing People's Hospital
No. 123, Baiyutan Road, Yuecheng District
Shaoxing
China
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
Jiaying First Hospital
No. 1882, Zhonghuan South Road
Jiaying
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
China
318000

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