# Perioperative respiratory therapy hierarchical management in enhanced recovery after surgery

| Submission date   | Recruitment status No longer recruiting                   | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------|---|--|--|--|
| 12/05/2025        |   | Protocol                                   |  |  |
| Registration date | Overall study status Completed Condition category Surgery | Statistical analysis plan                  |  |  |
| 16/05/2025        |   | Results                                    |  |  |
| Last Edited       |   | Individual participant data                |  |  |
| 17/09/2025        |   | [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 Huiging, Gehg@zju.edu.cn

## **Contact information**

#### Type(s)

Principal investigator

#### Contact name

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Public

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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.

#### -Control Group

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

#### -Experimental Group

#### 1. Aerosol Therapy AT

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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 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 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

#### **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             |