

Effectiveness of a perioperative respiratory care protocol in patients scheduled to receive major abdominal surgery

Submission date 15/07/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 25/07/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/04/2020	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Patients scheduled to have major abdominal surgery are at increased risk of postoperative pulmonary complications (PPCs), as the lung will be mechanically ventilated during anaesthesia, which could lead to collapse and invasion by pathogens. Therefore, it is vital to take measures to prevent PPCs through perioperative respiratory care (care during the time period surrounding and during the operation). This care is not individualized and is the same for all patients. However, PPCs and lung function can differ substantially between patients. Therefore, different perioperative respiratory care should be provided for different patients. This study aims to test whether using a protocol-based approach to tailor perioperative respiratory care to the patient can reduce the risk of PPCs.

Who can participate?

Patients scheduled to have major upper abdominal surgery

What does the study involve?

Participants are randomised into either the intervention or the control group.

Participants in the control group will receive the conventional treatment of deep breath and cough direction, where they are asked to take 10 deep breaths followed by 3 coughs.

The intervention group will receive perioperative hierarchical respiratory care, where they receive a score based on their lung function which is then used to determine the best course of treatment for them, with strategies including deep breathing, coughing, positive pressure ventilation and incentive spirometry.

What are the possible benefits and risks of taking part?

The benefit for participants is that by taking part they will receive detailed instructions for perioperative breathing training, and will receive an additional booklet containing these. There are no known risks to participants taking part in this study, as the strategies used in both groups are routinely performed within hospitals.

Where is the study run from?
Sir Run Run Shaw Hospital, Hangzhou, China

When is the study starting and how long is it expected to run for?
April 2018 to December 2019

Who is funding the study?
Sir Run Run Shaw Hospital (China)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
2018-01

Study information

Scientific Title
Perioperative Hierarchical respiratory Care for the prevention of respiratory Complications after Upper abdominal surgery: a randomized controlled study

Acronym
HICCUP

Study objectives
Perioperative Hierarchical respiratory care is able to reduce the risk of respiratory complications after upper abdominal surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the ethics committee of Sir Run Run Shaw hospital, 21/05/2018, 20180521-2

Primary study design

Interventional

Study design

Interventional randomised controlled single-center study

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Perioperative respiratory complications after abdominal surgery

Interventions

Participants will be randomly assigned to the intervention and control groups using central randomisation with a computer generated random number.

The control group will only receive the conventional treatment of deep breath and cough direction, where they are asked to take 10 deep breaths followed by 3 coughs.

The intervention group will receive perioperative hierarchical respiratory care, where participants are classified according to pulmonary function and are given a score of 0-10 based on this, which is then used to determine a strategy for bronchial hygiene and lung expansion.

Patients are classified using the following criteria:

1. Disease (bronchial hygiene)
2. Lung injury
3. Operation/neuromuscular status
4. Chest imaging
5. Airflow/breath sound
6. Respiratory type/breathing work
7. Effective coughing
8. Activity ability
9. Oxygen therapy level
10. Subextremal exercise test
11. Six minute walk
12. Pulmonary function test

Each criteria receives a score of 0-3 points, where 0 indicates "none", 1 indicates "mild", 2 indicates "moderate" and 3 indicates "severe". The scores are then added up to give a final score. Patients with a final score of 0-2 will receive conventional deep breath and cough direction. Patients with a final score of 3-4 will be given incentive spirometry if deep breath and cough direction cannot improve respiratory function. Patients with 5-6 points will be given positive ventilation. Patients with a score of 7 or high will be given positive ventilation and high flow oxygenation.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Perioperative pulmonary complications, defined by the occurrence of one or more of the following during the hospital stay or within 28 days of discharge (depending on which occurred first):

1. Pneumonia, the presence of radiological evidence of pulmonary infiltration associated with at least 2 of the following criteria:
 - 1.1. Purulent sputum
 - 1.2. Elevated body temperature (38.0 °C)
 - 1.3. Leukocytosis (25% above baseline preoperative value)
2. Tracheobronchitis, a marked increase in sputum production or presence of purulent sputum in a subject with a normal chest x-ray
3. Atelectasis with clinical percussion or radiological evidence of atelectasis associated with dyspnea
4. Acute respiratory failure or acute deficiency of gas exchange with necessity for invasive or noninvasive mechanical ventilation
5. Bronchoconstriction, the presence of wheezing associated with dyspnea requiring bronchodilator prescription or a change in preoperative bronchodilator dosage

Key secondary outcome(s)

1. Length of stay in ICU and hospital, measured after 90 days
2. Perioperative mortality, measured after 7 days
3. Cost of the total hospital stay (including cost of surgery and drugs)

Completion date

30/12/2019

Eligibility**Key inclusion criteria**

1. Aged 18 years or older
2. Awaiting elective upper abdominal surgery that required:
 - 2.1. General anaesthesia
 - 2.2. Minimum 5 day hospital stay
 - 2.3. 5 cm or longer incision above or extending above the umbilicus
3. Attended outpatient pre-admission assessment clinic

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

350

Key exclusion criteria

1. Pregnant
2. Neuromuscular disease
3. Systemic diseases without surgical conditions
4. Cannot cooperate as result of a consciousness disorder
5. Cannot provide informed consent

Date of first enrolment

15/09/2018

Date of final enrolment

30/06/2019

Locations**Countries of recruitment**

China

Study participating centre

Sir Run Run Shaw hospital

3#, east Qingchun Road

Hangzhou

China

310016

Sponsor information**Organisation**

sir Run-Run Shaw hospital, Zhejiang university school of medicine

ROR

<https://ror.org/00ka6rp58>

Funder(s)**Funder type**

Not defined

Funder Name

none

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 due to local policy for confidentiality of patients

IPD sharing plan summary

Not expected to be made available