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

Submission date	**Recruitment status**	[X] Prospectively registered
15/07/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/07/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/04/2020	Respiratory	[ ] 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 willy 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Interventional randomised controlled single-center study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 measure
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 repercussion 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

Secondary outcome measures
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)

Overall study start date
01/04/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

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
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310016

Sponsor information

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

Sponsor details
3#, east Qingchun Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type
Not defined

Funder Name
none

Results and Publications

Publication and dissemination plan
The results will be published in academic journal.

Intention to publish date
06/06/2019

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