Predictors for efficient ICU use after pulmonary surgery: a retrospective multicenter study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21274

Source
NTR

Brief title
PEFIPACS

Health condition

Pulmonary surgery, intensive care, effective intensive care use, adverse events

Sponsors and support

Primary sponsor: Amphia Hospital
Source(s) of monetary or material Support: Amphia Hospital

Intervention

Outcome measures

Primary outcome

-invasive mechanical ventilation (initiated on the ICU or continued from the operating theatre for at least 3 hours)

-non-invasive mechanical ventilation (use of continuous positive airway pressure)

-reintubation

-use of high-flow nasal oxygen therapy Optiflow)

-pneumothorax requiring (new) chest tube insertion or repositioning chest tube

-need for bronchoscopy

-bleeding requiring intervention (requiring surgery or transfusion of blood (clotting) products)

-reoperation

-supraventricular arrhythmia (new-onset atrial fibrillation or atrial flutter) with hemodynamic impairment

-congestive heart failure (pleural effusion or pulmonary edema requiring diuretic therapy)

-myocardial infarction (elevated hs-cTn in combination with clinical symptoms or electrocardiography changes)

-hemodynamic instability requiring the use of vasopressors or inotropes

Secondary outcome

-pneumonia (purulent sputum, positive sputum or blood culture and clinical symptoms such as cough, fever or consolidation on chest radiograph)

-pulmonary empyema (pleural effusion and the presence of pus on pleural aspiration, microorganism on pleural fluid culture or positive pleural fluid Gram stain)

-sepsis (qSOFA score ≥2 in response to an infection)

-wound infection (purulent drainage from superficial incision or deliberate opening of superficial incision by surgeon and pain, tenderness, swelling or redness)

-urinary tract infection (urinary tract symptoms or fever and urine culture with no more than 2 species of organisms identified with at least one of which is a bacterium of ≥105 CFU/ml)

-acute kidney injury (increase in serum creatinine by ≥ 26 µmol/l, a percentage increase in serum creatinine of more than or equal to 50% or oliguria of less than 0.5 ml/kg per hour for more than six hours within 48 hours)

-respiratory insufficiency (hypoxia or hypercapnia leading to ICU (re)admission)

-reoperation

-supraventricular arrhythmia (new-onset atrial fibrillation or atrial flutter)

-congestive heart failure (pleural effusion or pulmonary edema requiring diuretic therapy)

-acute respiratory distress syndrome (defined as diffuse inflammatory lung injury (onset over 1 week or less), bilateral opacities consistent with pulmonary edema must be present and may be detected on CT or chest radiograph, PF ratio <300mmHg with a minimum of 5 cmH20 PEEP (or CPAP) must not be fully explained by cardiac failure or fluid overload

-pulmonary embolus (filling defect ≥ 75% in a pulmonary artery with corresponding normal ventilation

-stroke (clinical diagnosis of acute transient ischemic attack (TIA) or cerebrovascular accident (CVA))

-myocardial infarction (elevated hs-cTn in combination with clinical symptoms or electrocardiography changes)

-mortality

Study description

Background summary

Rationale: It is unclear whether admission to an Intensive Care Unit (ICU) to prevent adverse events after pulmonary surgery is necessary.

Objective: To identify which patients may benefit from admission to the ICU after pulmonary surgery and to develop a clinical prediction model for future effective ICU use.

Study design: Multicenter retrospective cohort study.

Study population: Patients that underwent elective pulmonary surgery (pneumonectomy, (bi)(sleeve)lobectomy, segmentectomy), with a postoperative admission to the ICU.

Intervention: Not applicable.

Main study parameters/endpoints: Factors that pose an immediate threat to life.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Not applicable.

Study objective

Routine admission to the ICU after pulmonary surgery may not necessarily be required for each patient. The aim of this study is to identify which patients may benefit from admission to the ICU after pulmonary surgery and to develop a clinical prediction model for future effective ICU use.

Study design

primary endpoints are scored before 08.00 on the first postoperative morning and secondary endpoints are scored within 30 days of surgery

Intervention

not applicable

Contacts

Public
Amphia Hospital
Thijs Rettig
Breda
The Netherlands
0765955637
Scientific
Amphia Hospital
Thijs Rettig
Breda
The Netherlands
0765955637

Eligibility criteria

Inclusion criteria

Patients that underwent elective pulmonary surgery (pneumonectomy, (bi)(sleeve)lobectomy, segmentectomy), with a postoperative admission to the ICU are included.

Exclusion criteria

Intraoperative death.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2018
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7013
NTR-old	NTR7211
CCMO	NL2018.24.1.1

Study results