Inflammation and complications after pulmonary surgery for cancer

No registrations found.

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

Summary

ID

NL-OMON25075

Source
Nationaal Trial Register

Brief title
ICAPSUC

Health condition

pulmonary surgery, cancer, postoperative complications

longchirurgie, kanker, postoperatieve complicaties

Sponsors and support

Primary sponsor: Amphia Hospital
Source(s) of monetary or material Support: Amphia Hospital
St. Antonius Hospital
Roche

Intervention

Outcome measures

Primary outcome

Primary endpoint is the development of an infectious complication which is defined as one of

the following outcomes within 30 days of surgery:

- 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)

Secondary outcome

Secondary endpoint is the development of a non-infectious complication which is defined as one of the following outcomes within 30 days of surgery:

- 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: Up to half of patients undergoing pulmonary surgery for cancer suffer from complications such as pneumonia, sepsis and mortality. Early detection of complications may improve postoperative outcome.

Objective: To identify relative interleukin-6 (IL-6) thresholds (% increase from baseline within 24 hours and % decrease from the peak postoperative value) for predicting infectious, non-infectious and any complications after pulmonary surgery and to compare the diagnostic accuracy of relative IL-6 levels for predicting postoperative complications with other biomarkers.

Study design: Multicentre prospective observational cohort study.

Study population: 250 patients undergoing elective pulmonary surgery (pneumonectomy, (bi)(sleeve)lobectomy, segmentectomy for cancer with an American Society of Anesthesiologists (ASA) physical status classification ≥2.

Intervention: None.

Main study parameters/endpoints: The main study parameters are perioperative levels of interleukin (IL-6), C-reactive (CRP), leucocyte count, procalcitonin (PCT), pro brain natriuretic peptide (proBNP), growth differentiation factor-15 (GDF-15) and high-sensitive cardiac troponin (hs-cTn). Primary endpoint is the occurrence of an infectious complication. Secondary endpoints are non-infectious complications, any complication (a composite of infectious and non-infectious complications), length of Intensive Care Unit and length of hospital stay.

Study objective

Relative interleukin-6 (IL-6) thresholds (% increase from baseline within 24 hours and % decrease from the peak postoperative value) may predict infectious and non-infectious complications after pulmonary surgery better than perioperative levels of C-reactive (CRP), leucocyte count, procalcitonin (PCT), pro brain natriuretic peptide (proBNP), growth differentiation factor-15 (GDF-15) and high-sensitive cardiac troponin (hs-cTn).

Study design

Blood samples are drawn on the day of surgery immediately after induction of anesthesia and after 6, 9, 12 and on the morning of the first, second and third postoperative day.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

Elective pulmonary surgery (pneumonectomy, (bi)(sleeve)lobectomy, segmentectomy) for cancer, American Society of Anesthesiologists (ASA) physical status classification ≥2 with a planned postoperative admission to the Intensive Care.

Exclusion criteria

(suspected) Infection at the time of surgery and reoperation within 24 hours of surgery will be excluded from the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-07-2018
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	NL7172
NTR-old	NTR7363
CCMO	NL2017.20.9.1

Study results