Inflammation and complications after pulmonary surgery for cancer

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25075

Bron
Nationaal Trial Register

Verkorte titel
ICAPSUC

Aandoening

pulmonary surgery, cancer, postoperative complications

longchirurgie, kanker, postoperatieve complicaties

Ondersteuning

Primaire sponsor: Amphia Hospital
Overige ondersteuning: Amphia Hospital
St. Antonius Hospital
Roche

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7172
NTR-old	NTR7363
CCMO	NL2017.20.9.1

Resultaten