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

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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...

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

Samenvatting

ID

NL-OMON21274

Bron
NTR

Verkorte titel
PEFIPACS

Aandoening

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

Ondersteuning

Primaire sponsor: Amphia Hospital
Overige ondersteuning: Amphia Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Intraoperative death.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	500
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:	14-05-2018
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	NL7013
NTR-old	NTR7211
CCMO	NL2018.24.1.1

Resultaten