PEEP Optimization After Elective Cardiac Surgery: A Pilot Study

Published: 23-02-2024
Last updated: 02-12-2024

This study will initially focus on gaining insight into the difference between the current set PEEP level following cardiothoracic surgery compared to individually adjusting the PEEP level using EIT or Pes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56506

Source
ToetsingOnline

Brief title
PEEP optimization after elective Cardiothoracic surgery

Condition

- Other condition
- Respiratory tract therapeutic procedures

Synonym
Atelectasis, collapsed alveoli

Health condition

Cardio-thoracale chirurgische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiothoracic surgery, Elective, Optimization, PEEP

Outcome measures

Primary outcome

The difference in PEEP levels between the baseline setting and the PEEP level established after a decremental PEEP trial using EIT or Pes measurement.

Secondary outcome

* Driving pressure at a tidal volume of 6 ml/kg IBW (Ideal Body Weight).

* Dynamic compliance.

* End-expiratory lung volume (EELV).

* Global Inhomogeneity Index (GI).

* Hemodynamic parameters (arterial blood pressure, heart rate, central venous pressure (CVP)).

* P/F ratio (ratio of arterial oxygen tension to the fraction of inspired oxygen).

* Transpulmonary pressures (end-expiratory transpulmonary pressure, end-inspiratory transpulmonary pressure, transpulmonary driving pressure).

* Incidence of pneumonia, defined as received antibiotics with differential diagnosis of pneumonia, from day 2 till 5.

Study description

Background summary

Patients undergoing cardiothoracic surgical procedures face an elevated risk of pulmonary complications, ranging from hypoxemia to acute respiratory distress syndrome (ARDS). The most common complications include hypoxemia and the development of atelectasis. Having atelectasis poses a risk for the onset of pneumonia, a late complication of cardiothoracic surgery, which is associated with a poorer outcome. Atelectasis manifests as a decrease in lung compliance and a diminished ratio between arterial oxygen tension (pO2) and the fraction of inspired oxygen (FiO2); the P/F ratio.

Atelectasis can occur during the period when the patient is sedated and ventilated and/or during the post-extubation period. The risk of atelectasis during the ventilation period increases when the time on pressure control ventilation (PCV) is prolonged and/or when positive end-expiratory pressure (PEEP) is set too low.

The current PEEP level for patients with ARDS is set according to the ventilation protocol applicable in the Intensive Care Unit (ICU). This PEEP level can be adjusted in complex-to-ventilate patients using Electrical Impedance Tomography (EIT) or transesophageal pressure measurement (Pes). With Pes, the transpulmonary pressure corresponding to pleural pressure (PL) is measured.

Patients undergoing elective cardiothoracic surgical procedures rarely fall into the complex or prolonged ventilation category. At the same time, their P/F ratio is often equivalent to that associated with (mild) ARDS, given the incidence of atelectasis. The hypothesis is that, considering the occurrence of atelectasis, individually adjusting the optimal PEEP level using EIT or Pes in this patient group will lead to a reduction in atelectasis and a concomitant improvement in the P/F ratio.

Study objective

This study will initially focus on gaining insight into the difference between the current set PEEP level following cardiothoracic surgery compared to individually adjusting the PEEP level using EIT or Pes.

Study design

Randomized Pilot Study at Erasmus MC in Pressure-Controlled Ventilated Patients Following Elective Cardiothoracic Surgery in the ICU.

Intervention

Participants will be randomly allocated into two groups. One group will have their settings determined through Electrical Impedance Tomography (EIT) measurements, while the other group will have their settings determined through transesophageal pressure (Pes) measurements.

Study burden and risks

PCV (Pressure Control Ventilation) is standard care in the ICU after cardiothoracic surgery. Patients typically remain sedated and ventilated for an average of one to two hours before extubation. This study is not expected to cause significant delays in this process. Blood gas analysis to calculate the P/F ratio is routine care. Within the ventilation protocol, decremental PEEP trials, EIT measurements, and Pes measurements are included as interventions for challenging-to-ventilate patients. These interventions are not currently applied to the study population since they are generally extubated within a few hours. EIT and Pes measurements are used in this study because they provide the most reliable information for adjusting the optimal PEEP level.

The assessment is that this pilot study has a low burden with low risks. The interventions performed are already part of the ventilation protocol and are commonly carried out. The only difference now is that these interventions are performed in a different patient category. The risks of the interventions are:
* Risk of a nosebleed due to the insertion of the balloon catheter.
* A very small chance of pneumothorax due to the decremental PEEP trial that is conducted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Elective Cardiothoracic surgery
Older than 18 year

Exclusion criteria

* Transplantation surgery
* COPD GOLD III-IV
* Pneumothorax without a chest tube.
* Subcutaneous emphysema
* Open chest
* Chest wall abnormalities
* Hemodynamic instability
* Contraindications for inserting a nasogastric tube
* Pacemaker or implantable cardioverter defibrillator (ICD)

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	23-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-06-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL85657.078.24