PROtective ventilation with high versus low PEEP during one-lung ventilation for THORacic surgery - PROTHOR: A randomized controlled trial

Published: 05-09-2017
Last updated: 26-10-2024

To compare a strategy using high PEEP (10 cmH2O) with recruitment maneuvers versus low PEEP (5 cmH2O) without recruitment maneuvers, during thoracic surgery under standardized one lung ventilation with low VT (5 mL/kg predicted body weight - PBW) in…

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

Summary

ID

NL-OMON48913

Source
ToetsingOnline

Brief title
The PROTHOR Trial

Condition

- Other condition
- Procedural related injuries and complications NEC

Synonym
Mechanical ventilation; Lung function

Health condition

Mechanical one lung ventilation and post-operative Pulmonary complications

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Investigator Initiated Trial: No financing for this study.

Intervention

Keyword: One Lung Ventilation, Positive end-expiratory pressure:PEEP, Post-operative Pulmonary Complications: PPC, Thoracic surgery

Outcome measures

Primary outcome

The proportion of patients developing one or more PPCs

Secondary outcome

• intraoperative complications

• postoperative extra-pulmonary complications

• extended PPCs

• need for unexpected ICU admission or ICU readmission

• number of hospital-free days at day 28

• 90-day survival

• arterial blood gas analysis during OLV, TLV (pCO2, pO2, pH)

• any postoperative respiratory intervention (e.g. NIV or CPAP or intubation or

High Flow Nasal Cannula)

Study description

Background summary

One-lung ventilation (OLV) with resting of the contralateral lung may be required to allow or facilitate thoracic surgery. However, OLV can result in severe hypoxemia, requiring a mechanical ventilation approach that is able to maintain adequate gas exchange, while protecting the lungs against postoperative pulmonary complications (PPCs). During OLV, the use of lower tidal volumes (VT) is helpful to avoid over-distension, but can result in increased atelectasis and repetitive collapse-and-reopening of lung units, particularly at low levels of positive end-expiratory pressure (PEEP). Nevertheless, it is not known if, during OLV with low VT, high levels of PEEP combined with lung recruitment maneuvers are superior to low to moderate PEEP for protection against PPCs.

Study objective

To compare a strategy using high PEEP (10 cmH2O) with recruitment maneuvers versus low PEEP (5 cmH2O) without recruitment maneuvers, during thoracic surgery under standardized one lung ventilation with low VT (5 mL/kg predicted body weight - PBW) in adults.

Study design

An international multicenter double blind randomized controlled trial.

Intervention

Randomisation to high versus low PEEP during one-lung ventilation for Thoracic surgery

Study burden and risks

A particular advantage for all patients participating in this study is that they can benefit from extended monitoring during and after the operation. Nevertheless, there are different risks and benefits for both groups.

Low-pressure ventilation group: will be given the ventilation treatment that is preferred by most of the anesthesists all over the world. During low pressure ventilation, the oxygen content in the blood may be too low so that the respiratory gas mixture or respiratory pressure has to be adapted. A particular advantage of this form of ventilation is that the circulation is somewhat more stable.

Higher pressure ventilation: the air passages may well be held open, which is likley to help the transfer of oxygen. However, a transient drop in blood pressure may occur, which can be easily treated by the administration of specific drugs. These drugs occasionally lead to a reduction of the heart rate, which does not cause damage. If a situation develops with impaired lung

function or depression of the cardiocirculatory system, the applied ventilation pressure will be adapted to restore proper function.

The discharge from the hospital is not delayed due to participation in the study and no additional examinations after hosptal discharge are made.

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

• Patient scheduled for open thoracic or video-assisted thoracoscopic surgery under general anesthesia requiring OLV (no emergency surgery)
• BMI < 35 kg/m2
• age >= 18 years
• expected duration of surgery > 60 min

• planned lung separation with double lumen tube (DLT, not for study purpose only)
• most of ventilation time during surgery expected to be in OLV

Exclusion criteria

• COPD GOLD grades III and IV, lung fibrosis, documented bullae, severe emphysema, pneumothorax
• uncontrolled asthma
• Heart failure NYHA Grade 3 and 4, Coronary Heart Disease CCS Grade 3 and 4
• previous lung surgery
• documented pulmonary arterial hypertension >25mmHg MPAP at rest or > 40 mmHg syst. (estimated by ultrasound)
• documented or suspected neuromuscular disease (thymoma, myasthenia, myopathies, muscular dystrophies, others)
• planned mechanical ventilation after surgery
• bilateral procedures
• lung separation with other method than DLT (e.g. difficult airway, tracheostomy)
• surgery in prone position
• persistent hemodynamic instability, intractable shock
• intracranial injury or tumor
• enrollment in other interventional study or refusal of informed consent
• pregnancy (excluded by anamnesis and/or laboratory analysis)
• esophagectomy, pleural surgery only, sympathectomy surgery only, chest wall surgery only, mediastinal surgery only, lung transplantation
• presence before induction of anaesthesia of one of the adverse events, listed as postoperative pulmonary complications (aspiration, moderate respiratory failure, infiltrates, pulmonary infection, atelectasis, cardiopulmonary edema, pleural effusion, pneumothorax, pulmonary embolism, purulent pleuritis, lung hemorrhage)
• documented preoperative hypercapnia > 45mmHg (6kPa)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-09-2017
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02963025
CCMO	NL62625.018.17