Pulmonary Inflammation during Mechanical Ventilation of Patients with Healthy Lungs.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28818

Source
Nationaal Trial Register

Brief title
HiLoHelu

Health condition

Patients that are scheduled for surgical procedure of > 5 hours.

Sponsors and support

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

1. Local levels of cytokines;

2. Neutrophil influx;

3. Activation of coagulation/inhibition of fibrinolysis;

4. Ex vivo stimulation of alveolar macrophages;

5. Systemic levels of biomarkers of lung injury.

Secondary outcome

N/A

Study description

Background summary

Lung protective mechanical ventilation, using lower tidal volumes and sufficient levels of PEEP has been shown to be beneficial for patients with ALI or ARDS.
It is hypothesized that mechanical ventilation using lower tidal volumes and PEEP causes less local inflammation in patients with healthy lungs than mechanical ventilation using traditional tidal volumes and no PEEP.

For this, 40 patients with healhy lungs are randomized to be either mecahnically ventilated with a so-called protective strategy or with a conventional strategy.

Study objective

It is hypothesized that mechanical ventilation using lower tidal volumes and PEEP causes less local inflammation in patients with healthy lungs than mechanical ventilation using traditional tidal volumes and no PEEP.

Study design

N/A

Intervention

Mechanical ventilation using lower tidal volumes (6 ml/kg) and 10 cm H2O PEEP versus mechanical ventilation using traditional tidal volumes (12 ml/kg) and no PEEP.
Broncholaveoalr lavage at T = 0 and at T = 5 hours.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients that are scheduled for surgical procedure of > 5 hours;

2. Healthy pulmonary condition;

3. 18 years of age;

4. informed consent.

Exclusion criteria

1. Sepsis or uncontrolled infection;

2. ALI/ARDS;

3. Pneumonia;

4. Steroid-use;

5. Diagnosis of asthma;

6. Pulmonary fibrosis;

7. Current thrombo-embolism;

8. On daily medication for COPD;

9. Mechanical ventilation for > 48 hours in the month prior to surgery;

10. Pneumonectomy/lebectomy;

11. Participation in another trial;

12. Previous randomisation in present trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2003
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	23-08-2005
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	NL104
NTR-old	NTR135
Other	: N/A
ISRCTN	ISRCTN77539853

Study results

Summary results
Anesthesiology. 2008 Jan;108(1):46-54.