Protective mechanical ventilation during surgery on the abdomen with general anesthesia.

No registrations found.

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

Summary

ID

NL-OMON23359

Source
Nationaal Trial Register

Brief title
PROVHILO

Health condition

Post-operative respiratory failure

Intervention

Outcome measures

Primary outcome

Postoperative pulmonary complications:

1. Mild or severe respiratory failure;

2. ALI/ARDS;

3. Suspected pulmonary infection;

4. Pulmonary infiltrate on chest X-ray;

5. Atelectasis;

6. Pneumothorax;

7. Bronchospasm;

8. Aspiration pneumonitis;

9. Cardiopulmonary edema.

Secondary outcome

1. Intra–operative complications (desaturation, barotrauma, hypotension during recruitment, need for vasopressors);

2. Need for ICU admission (if not as part of routine) or ICU readmission;

3. Hospital–free days at day 90;

4. Post–operative non–pulmonary organ function;

5. Post–operative wound healing;

6. Systemic levels of markers of pulmonary inflammation, acute lung injury and markers of distal organ injury.

Study description

Background summary

Background of the study:

Post-operative respiratory failure, in particular after abdominal surgery and general anesthesia > 2 hours, adds to morbidity and mortality of surgical patients. Lung-protective mechanical ventilation, with the use of positive end-expiratory
pressure (PEEP) and recruitment maneuvers, has the potential to prevent lung injury in patients with injured lungs. It is the
question whether PEEP and recruitment also protects the lungs in patients without previous lung injury.

Objective of the study:

The present study aims at comparing the post-operative lung injury of a lung-protective mechanical ventilation strategy
(with the use of higher levels of PEEP and intra-operative recruitment maneuvers) with conventional mechanical
ventilation (lower levels of PEEP without recruitment) during abdominal non-laparoscopic surgery in patients at high or
intermediate risk for post-operative respiratory failure.

Study design:

Multinational multicentre randomized controlled trial.

Study population:

In total: 900 patients.

In The Netherlands: 100 patients.

Intervention:

The conventional group will be ventilated with low PEEP (maximum 2cm H2O), without recruitment.
The interventional groep will be ventilated with higher PEEP (12cm H2O), with intra-operative recruitment
maneuvres.

Primary study parameters/outcome of the study:

Post-operative pulmonary complications (for definitions see appendix ii):
Mild respiratory failure, severe respiratory failure, ALI/ARDS, suspected pulmonary infection, pulmonary infiltrate, pleural
effusion, atelectasis, pneumothorax, bronchospasm, aspiration pneumonitis, cardiopulmonary edema.

Secundary study parameters/outcome of the study:

Intra-operative complications, need for ICU admission (if not as part of routine) or ICU readmission, hospital-free days at
day 90, post-operative non-pulmonary organ function (see appendix ii); post-operative wound healing; systemic levels of
markers of pulmonary inflammation, acute lung injury and markers of distal organ injury.

Study objective

Post–operative respiratory failure, in particular after abdominal surgery and general anesthesia, adds to morbidity and mortality of surgical patients. Lung–protective mechanical ventilation, with the use of positive end–expiratory pressure (PEEP) and recruitment maneuvers, has the potential to prevent lung injury in patients with injured lungs. It is the question whether PEEP and recruitment also protects the lungs in patients without previous lung injury.

Study design

1. Pre-operative;

2. Per-operative;

3. Post-operative on day 1, 2, 3, 4 and 5.

Intervention

1. The conventional group will be ventilated with low PEEP (max 2cm H2O), without recruitment;

2. The interventional groep will be ventilated with higher PEEP (12cm H2O), with intra-operative recruitment maneuvres.

Contacts

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Eligibility criteria

Inclusion criteria

1. Planned elective abdominal surgery;

2. General anesthesia with intravenous medication;

3. High or intermediate risk for postoperative pulmonary complications.

Exclusion criteria

1. Age < 18 years;

2. Body mass index > 40 kg/m2;

3. Laparoscopic surgery;

4. Previous lung surgery (any);

5. Persistent hemodynamic instability, intractable shock (considered hemodynamic unsuitable for the study by the patient’s managing physician);

6. History of previous severe chronic obstructive pulmonary disease (COPD) (non–invasive ventilation and/or oxygen therapy at home, repeated systemic corticosteroid therapy for acute exacerbations of COPD);

7. Recent immunosuppressive medication (patients receiving chemotherapy or radiation therapy, less than 2 months after chemotherapy or radiation therapy);

8. Severe cardiac disease (New York Heart Association class III or IV, or acute coronary syndrome, or persistent ventricular tachyarrhythmia’s);

9. Mechanical ventilation > than 30 minutes (e.g., in cases of general anesthesia because of surgery) within last 30 days;

10. Pregnancy (excluded by laboratory analysis);

11. Acute lung injury or acute respiratory distress syndrome expected to require prolonged postoperative mechanical ventilation;

12. Neuromuscular disease (any);

13. Consented for another interventional study or refusal to participate in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	900
Type:	Actual

Ethics review

Positive opinion

Date:	16-09-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36531
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2409
NTR-old	NTR2517
CCMO	NL33848.018.10
ISRCTN	ISRCTN70332574
OMON	NL-OMON36531

Study results

Summary results
Hemmes et al, Trials 2011, 12:111