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

Gepubliceerd: 16-09-2010 Laatst bijgewerkt: 19-03-2025

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)...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23359

Bron
Nationaal Trial Register

Verkorte titel
PROVHILO

Aandoening

Post-operative respiratory failure

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Pre-operative;

2. Per-operative;

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Planned elective abdominal surgery;

2. General anesthesia with intravenous medication;

3. High or intermediate risk for postoperative pulmonary complications.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	900
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36531
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
Hemmes et al, Trials 2011, 12:111