The full closed loop ventilation mode Intellivent-ASV: user-friendly and effective mechanical ventilation in high risk postoperative patients on the intensive care unit.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27583

Source
NTR

Health condition

Intellivent-ASV ventilation mode
Fully closed loop ventilation
Conventional ventilation mode
Postoperative ventilation

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The effectiveness of IntelliVent-ASV compared to conventional mechanical ventilation:

1. Percentage of mechanical ventilation time in an optimal, acceptable or unacceptable zone.

2. The number of successful extubations (without new intubation <48 hours) within 24 hours, 36uur and 48 hours after surgery.

3. Mechanical ventilation time to extubation measured from the time that the patient has a temperature> 35.5 ° C.

User-friendliness of IntelliVent-ASV compared to conventional mechanical ventilation:

1. Based on the measurement of the number of interactions between the caregiver and the ventilator.

2. Survey of usability and acceptance for the caregivers.

Secondary outcome

The safety of IntelliVent-ASV compared to conventional mechanical ventilation:

1. Percentage of mechanical ventilation time with an oxygen saturation <85%.

2. Percentage of mechanical ventilation time in an unacceptable zone.

Reliability of non-invasive measurements by the ventilator:

1. Comparison of the end tidal CO2 and oxygen saturation measured by the mechanical ventilator and the arterial blood gases.

2. Percentage of mechanical ventilation time with the oxygen saturation not measurable.

The patient friendliness of IntelliVent-ASV compared to conventional mechanical ventilation:

1. The number, by the caregiver, established agitated moments of the patient.

2. The number of administrations of opiates, benzodiazepines or haloperidol.

Postoperative shunting during and after mechanical ventilation:

1. The end tidal CO2 and pCO2, pO2 / FiO2 ratio in arterial blood gases; after about 1 hour, 12
hours, 24 hours, and 0.5 till 4 hours after extubation.

2. The number of patients with pulmonary atelectasis described on the X-rays of the thorax within 48 hours after surgery.

Study description

Background summary

Objective of the study:

The aim of this study is to investigate whether postoperative ventilation with IntelliVent ASV in high risk patients, after cardio-thoracic and abdominal surgery, is as effective, more user-friendly and as safe as compared to the conventional modes of ventilation.

Study design:

This is a prospective randomized study with a control group and a treatment group of postoperative high risk patients. Through randomization will be determined whether the participant, after surgery, will be mechanically ventilated with IntelliVent-ASV and Quickwean or with conventional mechanical ventilation.

Study population:

The study population consists high risk patients after cardio-thoracic or abdominal surgery. These patients were assessed before surgery, according to protocol, to be mechanically ventilated after surgery on the high care unit of the intensive care ward, until they can be extubated.

Study design

Primairy outcomes:

- Effectiveness.

1: Percentage of mechanical ventilation time in an optimal, acceptable or unacceptable zone., Timepoints: 48 hours of ventilation;

2: Successful extubations: 48 hours after surgery;

3: Mechanical ventilation time: until extubation or death.

- User-friendliness.

1: Interactions with ventilator: 48 hours;

2: Survey: <24 hours after working with ventilator.

Secondary outcomes:

- Safety.

1: Oxygen saturation <85%: 48 hours of ventilation;

2: Ventilation in an unacceptable zone: 48 hours of ventilation.
- Reliability

1: End tidal CO2 en oxygen saturation: 48 hours of ventilation;

2: Unmeasurable oxygen saturation: 48 hours of ventilation.

- Patient friendliness

1: Agitated moments: 48 hours of ventilation;

2: Opiates, benzodiazepines or haloperidol administration: 48 hours of ventilation.

- Postoperative shunting:

1: End tidal CO2, pCO2, pO2 / FiO2 ratio: until 4 hours after extubation;

2: Postoperative pulmonary atelectasis: <48 hours after surgery.

Intervention

- The intervention group will be mechanically ventilated with IntelliVent-ASV after surgery.

- The control group will be mechanically ventilated based on the conventional method, consisting out of pressure or volume-controlled mechanical ventilation, followed by pressure support.

Contacts

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Eligibility criteria

Inclusion criteria

- Age above 18 years of age.

- Informed consent.

- Body mass index of <35 kg/m2.

- Mechanical ventilation after elective surgery.

- Admission of the patient after surgery is on the high care unit of the intensive care ward for postoperative mechanical ventilation.

Exclusion criteria

- The patient with a medical history of a pneumonectomy or lobectomy.

- The patient wit acute respiratory distress syndrome after surgery.

- The patient with a medical history of COPD Gold 3 or 4.

- The patient is participating in an other postoperative study performed on the intensive care.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-10-2016
Enrollment:	400
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5779
NTR-old	NTR6061

Register	ID
Other	NL58975.100.16 : ARB-code

Study results