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

Published: 10-11-2016
Last updated: 15-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45718

Source
ToetsingOnline

Brief title
'POSiTIVE'-trial (POSToperative Intellivent VEntilation)

Condition

- Other condition

Synonym
Postoperative mechanical ventilation and weaning. Mechanical ventilation after surgery.

Health condition

Intensive Care geneeskunde, postoperatieve mechanische ventilatie

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina Ziekenhuis Eindhoven

Intervention

Keyword: Conventional ventilation mode, Fully closed loop ventilation, INTELLiVENT-ASV ventilation mode, Postoperative ventilation

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 for the first three hours of postoperative mechanical

ventilation time after admission on the intensive care unit.

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 and semistructured interviews 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 for the first three hours of postoperative mechanical ventilation time after admission on the intensive care unit.

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.

3. RASS score: every hour until extubation or reoperation for the first 48 hours after elective surgery.

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

Recently, Hamilton Medical has introduced the new mechanical ventilation mode "INTELLiVENT-ASV". This is a fully closed ventilation mode that can automatically adjust the ventilation settings based on the measured End tidal CO2 (ETCO2) and the measured saturation (SpO2) in both passive and active ventilated patients. Current literature has shown that this mode is safe to use in patients admitted on the intensive care unit.
A pilot study in the Catharina Hospital Eindhoven confirmed that in postoperative low risk patients on the intensive care unit INTELLiVENT-ASV is safe. Compared to continuous mandatory or pressure controlled ventilation with pressure support (conventional mechanical ventilation), INTELLiVENT-ASV is even as effective as conventional mechanical ventilation, with a significantly reduced number of interactions with the ventilator.
However, available research about the effectiveness of INTELLiVENT-ASV in postoperative high risk patients is lacking. Also the knowledge about the user-friendliness of the above modes of mechanical ventilation for the users is lacking.

Study objective

The aim of this study is to investigate whether postoperative ventilation with INTELLiVENT-ASV in high risk patients, after cardio-thoracic 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.

Intervention

- The intervention group will be mechanically ventilated with INTELLiVENT-ASV with Quickwean 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.

Study burden and risks

During this study, there will be no increased risk to the patient. The postoperative mechanical ventilation will be performed with ventilating modes that are available on a CE approved ventilator of Hamilton. The caregiver will be subjected to use a particular ventilating mode that was assigned to the participating patient (INTELLiVENT-ASV with Quickwean or conventional mechanical ventilation).

No additional invasive measurements will be done during the study.

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

Age above 18 years of age.
Informed consent.
Body mass index of <35 kg/m2.
Mechanical ventilation after elective cardiothorarcic surgery.
Admission of the patient after surgery is on the high care unit of the intensive care ward for postoperative mechanical ventilation.

Exclusion criteria

Withdrawal of consent
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 another postoperative study performed on the intensive care.
The patient is, preoperatively determined, eligible for a shorttrack postoperative treatment program on the Post Anesthesia Care Unit.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2017
Enrollment:	250

Type:	Actual

Medical products/devices used

Generic name:	Mechanical ventilator Hamilton S1
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-11-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL58975.100.16

Study results

Date completed:	17-05-2018
Actual enrolment:	220