POStoperative INTELLiVENT-adaptive support VEntilation in cardiac surgery patients II (POSITiVE II) - a randomized clinical trial

Published: 30-09-2024
Last updated: 27-12-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON57027

Source
ToetsingOnline

Brief title
POSITiVE II

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
cardiac surgery, Mechanical ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Medical University Wien
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Closed-loop ventilation, Critical care, Mechanical ventilation, Workload

Outcome measures

Primary outcome

The primary outcome is quality of ventilation, which is the proportion of time spent in three predefined and previously used zones of ventilation (see Appendix 13.1) in the first 2 hours of postoperative ventilation, as used before in previous studies of automated ventilation.

See chapter 6.2 in protocol.

Secondary outcome

One main secondary endpoint is:

• ICU nursing staff workload, which is captured by the ventilator software collecting data on alarms (number of alarms, types of alarm, duration of alarm, responses to alarm, alarm settings and adjustments, breath-by-breath alarm data, and any manual intervention at the ventilator) during postoperative care in the ICU, as used before in previous studies;

Other secondary endpoints are:

• duration of postoperative ventilation;

• patient-ventilator asynchrony requiring deepening of sedation and/or

administration of muscle relaxants;

• proportion of breath spent in zones of ventilation;

• postoperative pulmonary complications;

• ICU length of stay;

• hospital length of stay; and

• mortality in ICU and hospital.

Study description

Background summary

1.1 Postoperative ventilation
Postoperative ventilation is often needed after cardiac surgery. Over the last decades it has become increasingly clear that ventilation has a strong potential to injure the lungs, and emphasis has been put on using lung-protective ventilator settings. Lung-protective ventilation consists of ventilation using a properly-sized tidal volume (VT) to prevent volutrauma and barotrauma, applying low pressures and energy to avoid energy trauma, and restrictions in the use of oxygen to minimize the risk of chemotrauma.

1.2 ICU nursing staff workload
Applying lung-protective ventilation can be challenging and is often time-consuming, as it requires complex titrations of ventilator settings according to changing and individual needs of a patient, also in patients after cardiac surgery. This is important in intensive care units (ICUs) that are facing increasing challenges due to shortages in nursing staff, in particular during surges of patients in need for respiratory support, as witnessed in the recent coronavirus disease 2019 pandemic. Diminished ICU nursing staff is a growing problem, and every effort should be taken to reduce the workload of often overtasked and overcharged ICU nurses.

1.3 Automated, or closed-loop ventilation
Automated, or closed-loop ventilation is increasingly attractive for clinical use, as it improves the quality of ventilation and potentially offers support to diminished ICU nursing staff. Closed-loop modes are progressively available on ventilators for use in critically ill patients. With INTELLiVENT-Adaptive Support Ventilation (ASV), one of the most sophisticated forms of closed-loop ventilation, those ventilator settings that are typically under control of the ICU nursing staff are under control of algorithms that form the basis of this

form of closed-loop ventilation. INTELLiVENT-ASV targets ventilation and oxygenation goals based on lung mechanics, whereby it adjusts, breath-by-breath, VT, respiratory rate (RR), positive end-expiratory pressure (PEEP), and fraction of oxygen in inspired air (FiO2). Furthermore, INTELLiVENT-ASV facilitates weaning by using a weaning protocol and spontaneous breathing trials. Several studies have shown INTELLiVENT-ASV to be safe and effective with regard to lung-protective ventilation.

Study objective

The here proposed randomized clinical trial, named *POStoperative INTELLiVENT-adaptive support VEntilation in cardiac surgery patients II* (POSITiVE II), compares INTELLiVENT-ASV with conventional ventilation in patients planned for elective cardiac surgery and expected to need postoperative ventilation in an intensive care unit for at least 2 hours.
2.1 Primary objective
The primary objective is to compare the two ventilation strategies with respect to quality of ventilation.
2.2 Secondary objectives
One major secondary objective is to compare the two ventilation strategies with respect to ICU nursing staff workload, using time and motion observations; we will also compare the two ventilation strategies with respect to patient-centered endpoints like duration of ventilation, and length of stay in ICU.
2.3 Hypotheses
We hypothesize that INTELLiVENT-ASV is superior to conventional ventilation with respect to the quality of ventilation in postoperative ventilation in patients after cardiac surgery. We further hypothesize that INTELLiVENT-ASV is non-inferior to, i.e., as good as conventional ventilation with respect to duration of ventilation and length of stay in ICU.

Study design

POStoperative INTELLiVENT-adaptive support VEntilation in cardiac surgery patients II (POSITiVE II) is an investigator-initiated, international, multicenter, parallel, randomized clinical trial in patients after cardiac surgery. The study will be conducted according to the Good Clinical Practice-guidelines and comply with the principles of the Declaration of Helsinki, national and international regulatory requirements and general data protection regulations. The study is registered in a public registry and the study protocol with its statistical analysis plan will be prepublished.

Intervention

The intervention tested is named *INTELLiVENT-ASV*, a closed-loop mode of ventilation available at Hamilton Medical AG ventilators (Hamilton Medical AG, Bonaduz, Switzerland) and intended to be used in patients that need ventilation

in an intensive care unit (ICU). INTELLiVENT-ASV is a fully automated mode of ventilation, targeting the lowest work and force of breathing, through breath-by-breath adaptation of tidal volume (VT) and respiratory rate (RR), and positive end-expiratory pressure (PEEP) and fraction of inspired oxygen (FiO2) based on patient activity, airway pressures and continuous pulse oximetry readings and end- tidal carbon dioxide monitoring. It also uses a weaning protocol and spontaneous breathing trials to facilitate weaning.

Study burden and risks

Patient burden and risks are low, the collection of general data from hospital charts and (electronic) medical records systems causes no harm to the patients; the patient will not experience any discomfort because they are still sedated during postoperative ventilation in the ICU. INTELLiVENT-ASV and conventional ventilation are standard care, but will be protocolized in this 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

1. aged > 18 years of age;
2. scheduled for elective cardiac surgery; and
3. expected to receive postoperative ventilation in the ICU for > 2 hours.

Exclusion criteria

1. any emergency or semi-elective surgery (precluding informed written consent);
2. any surgery other than CABG, valve replacement or repair, or a combination (i.e., patients planned for surgery for congenital heart disease, or scheduled for heart transplantation are excluded);
3. enrolled in another interventional trial;
4. no written informed consent obtained;
5. history of recent pneumectomy or lobectomy;
6. history of COPD with oxygen at home;
7. body mass index > 35;
8. preoperative forced expiratory volume in the first second (FeV1)/forced vital capacity (VC) < 50% (if available);
9. preoperative arterial oxygen partial pressure (PaO2) < 60 mm Hg (at room air);
10. preoperative arterial carbon dioxide partial pressure (PaCO2) > 50 mm Hg;
11. preoperative left ventricular ejection fraction < 30% (if available);
12. preoperative systolic pulmonary artery pressure > 60 mm Hg (if available);
13. preoperative left ventricular mechanical support, e.g., Impella®; or
14. preoperative use of veno-venous or veno-arterial extracorporeal support

end of surgery,
patients are additionally excluded if a patient:
15. cannot be weaned from the extracorporeal support; or
16. unexpectedly needs implementation of an assist device

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	110
Type:	Anticipated

Medical products/devices used

Generic name:	Ventilator Hamilton C6 / G5
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-09-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT06178510

Register	ID
CCMO	NL86097.018.24