Effect of Automated Closed-loop Ventilation versus Conventional Ventilation on Duration and Quality of Ventilation (*ACTiVE*) -a randomized clinical trial in intensive care unit patients

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To compare automated closed-loop ventilation (INTELLiVENT-ASV) to conventional, non-automated ventilation in patients in the ICU.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON52461

Source
ToetsingOnline

Brief title
ACTiVE

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
respiratory insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: artificial, INTELLiVENT-ASV, intensive care, respiration

Outcome measures

Primary outcome

The primary endpoint is the number of ventilator-free days and alive at day 28 after ICU admission. The co-primary endpoint is the quality of breathing, defined as time spent within predefined zones of optimal ventilation.

Secondary outcome

Secondary study parameters include:

- ICU length of stay

- Hospital length of stay

- 28-day mortality

- 90-day mortality

- Incidence of ICU mortality

- Incidence of hospital mortality

- Incidence of: development of Acute Respiratory Distress Syndrome (ARDS), pneumonia, severe atelectasis, pneumothorax, respiratory muscle weakness, severe hypoxemia and severe hypercapnia

- Incidence of use of rescue therapies for severe hypoxemia or severe atelectasis (e.g. recruitment maneuver, prone positioning, bronchoscopy for opening atelectasis)

- Quality of life at day 28

Study description

Background summary

INTELLiVENT-adaptive support ventilation (ASV) is an automated closed-loop ventilation mode, in which ventilator settings are continuously and automatically adjusted in accordance to a set of broadly accepted guidelines for invasive ventilation and in response to feedback which the machine uninterruptedly receives regarding the situation of the patient. While the safety and feasibility of INTELLiVENT-ASV has been confirmed in several studies, robust evidence for clinical benefit in comparison to conventional ventilation is currently missing. The here proposed investigator-initiated international multicenter randomized clinical trial will provide high-level evidence for clinical benefit of INTELLiVENT-ASV in a general population of invasively ventilated intensive care unit (ICU) patients.

Study objective

To compare automated closed-loop ventilation (INTELLiVENT-ASV) to conventional, non-automated ventilation in patients in the ICU.

Study design

International, multicenter, superiority, randomized controlled trial in intubated and ventilated adult ICU patients.

Intervention

Patients randomized to the automated closed-loop ventilation-arm are ventilated with INTELLiVENT-ASV mode; patients randomized to the conventional ventilation-arm are ventilated with a non-automated mode of ventilation.

Study burden and risks

Differences in burden and risk of the two ventilation strategies are not expected. Both methods of ventilation are currently used as standard care on the intensive care unit. No other study interventions are performed. Collection of demographic data, ventilation data and outcome data causes no harm for the patients.

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

- Admission to an ICU participating in this trial
- Need for invasive ventilation
- An expected duration of ventilation > 24 hours

Exclusion criteria

- Age less than 18 years
- Invasive ventilation longer than 1 hour in the intensive care unit before randomization
- Invasive ventilation longer than 6 hours directly preceding intensive care unit admission

- Patients who have recently undergone a pneumectomy or lobectomy
- Patients with suspected or confirmed pregnancy
- Patients with morbid obesity (body mass index > 40)
- Patients with premorbid restrictive pulmonary disease (evidence of chronic interstitial infiltration on chest radiographs)
- Patients in whom pulse oximetry is known to be unreliable (e.g., patients with carbon monoxide
poisoning)
- Patients with any neurologic diagnosis that can prolong duration of mechanical ventilation (e.g., patients with Guillain-Barré syndrome, high spinal cord lesion or amyotrophic lateral sclerosis, multiple sclerosis, or myasthenia gravis)
- Patients receiving veno-venous, veno-arterial or arterio-venous extracorporeal membrane
oxygenation (ECMO)
- Previous randomization in this randomized controlled trial
- Patients participating in another study with the same endpoint or interventions possibly
comprising this study outcome
- No informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-10-2020
Enrollment:	1040
Type:	Actual

Medical products/devices used

Generic name:	Intellivent-ASV closed-loop mechanical ventilation

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL72786.018.20