Mechanical Power under Closed-loop versus Conventional Ventilation - a multicenter crossover randomized clinical trial.

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To compare MP under INTELLiVENT-adaptive support ventilation (ASV), a fully-automated closed-loop ventilation, with MP under conventional ventilation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON52209

Source
ToetsingOnline

Brief title
INTELLiPOWER

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: Ministerie van OC&W

Intervention

Keyword: Closed-loop ventilation, Critical Care, Mechanical Power, Mechanical ventilation

Outcome measures

Primary outcome

The primary endpoint is the amount of MP with each form of invasive

ventilation.

Secondary outcome

N.a.

Study description

Background summary

Mechanical ventilation can cause ventilator-induced lung injury (VILI). Lung protective ventilation, consisting of a low tidal volume (VT), a low plateau pressure (Pplateau) and a low driving pressure (ΔP) improves survival and shortens duration of ventilation in patients with acute respiratory distress syndrome (ARDS), and may also benefit critically ill patients with respiratory failure not caused by ARDS. *Mechanical Power of ventilation* (MP), the amount of energy per time transferred from the ventilator to the respiratory system, is a summary variable that includes all the components that play a role in VILI. With fully-automated closed-loop ventilation, all these components are no longer set by the operator, but under control of the algorithms in the ventilator.

Study objective

To compare MP under INTELLiVENT-adaptive support ventilation (ASV), a fully-automated closed-loop ventilation, with MP under conventional ventilation.

Study design

International, multicenter, crossover, randomized clinical trial.

Intervention

The ventilator will be randomly switched between INTELLiVENT-ASV for 3 hours and conventional ventilation for 3 hours.

Study burden and risks

Differences in burden and risks of the two ventilation strategies compared in this study are not expected. Both modes of ventilation are currently interchangeably used as part of standard care in the participating centers. No other interventions are performed. Collection of demographic data, ventilation data and outcome data, causes no harm to the patient.

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

• Admitted to one of the participating ICUs;
• Receiving invasive ventilation through a standard endotracheal tube;
• Expected to be ventilated > 24 hours;
• Ventilation with a ventilator that provides INTELLiVENT-ASV.

Exclusion criteria

• Age under 18 years of age;
• No written informed consent;
• Morbidly obese;
• Any contra-indications for use of INTELLiVENT-ASV

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2021
Enrollment:	84
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	26-02-2021
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
CCMO	NL74931.018.20