Does Automated closed-loop ventilation Reduce the DRiving Pressure levels in patients with ARDS (AiRDRoP) - an international multi-center crossover study and randomized controlled trial

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The objective of this crossover study and randomized controlled trial is to compare ΔP levels during INTELLiVENT®-ASV with conventional lung protective ventilation in patients with moderate or severe ARDS.

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

Summary

ID

NL-OMON46892

Source
ToetsingOnline

Brief title
AiRDRoP

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
acute lung injury, ARDS

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ARDS, Driving pressure, Intellivent-ASV, Mechanical ventilation

Outcome measures

Primary outcome

Transpulmonary driving pressure

Secondary outcome

- End expiratory pressure in the respiratory system

- End expiratory pressure in the esophagus

- End inspiratory pressure in the respiratory system

- End inspiratory pressure in the esophagus

- tidal volume (Vt)

- positive end-expiratory pressure (PEEP)

- plateau pressure (Pplat)

- peak pressure (Ppeak)

- respiratory rate (RR)

- fraction of inspired oxygen (FiO2)

- exhaled CO2 (etCO2 en VCO2)

- peripheral oxygen saturation (spO2)

- CO2 tension in arterial blood (PaCO2)

- oxygen tension in arterial blood (PaO2)

- oxygen saturation in arterial blood (saO2)

- pH of arterial blood

- bicarbonate in arterial blood (HCO3)

Study description

Background summary

Mechanical ventilation is a mandatory intervention in patients with acute respiratory distress syndrome (ARDS). Mechanical ventilation can cause or worsen lung injury. Additional lung injury is partly prevented by using low driving pressures (<15cm H2O). There are strong indications that an automated ventilation modality, INTELLiVENT-ASV, leads to a lower driving pressure than in conventional lung protective ventilation. Esophageal pressure measurement can help differentiate between pleural and alveolar pressure; only alveolar pressure is associated with lung injury.

Study objective

The objective of this crossover study and randomized controlled trial is to compare ΔP levels during INTELLiVENT®-ASV with conventional lung protective ventilation in patients with moderate or severe ARDS.

Study design

International multi-center crossover study and randomized controlled trial.

Intervention

One group will be ventilated with INTELLiVENT-ASV, the other group will be ventilated with conventional lung protective ventilation. Extra esophageal pressure measurements will be performed.

Study burden and risks

INTELLiVENT®-ASV has been found to be a safe and efficient ventilatory mode in patients with ARDS, and to be at least as safe as conventional lung protective ventilation. The burden and risks of ventilation with INTELLiVENT®-ASV are comparable to that of conventional lung protective ventilation. The extra esophageal pressure measurements will not cause extra burden and risks for the subjects. The intervention can lead to a reduction in transpulmonary driving pressure, this can benefit 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

- Moderate/severe ARDS
- Intubated and ventilated
- Within 24 hours of initial diagnosis of ARDS

Exclusion criteria

- Age <18
- Previously included in this study or other interventional trial that could influence ventilation parameters
- Suspected or confirmed pregnany
- Increased or uncontrollable intracranial pressure

- Contra-indication for esophageal pressure measurement

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	INTELLiVENT-ASV
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-04-2017
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	NCT03211494
CCMO	NL56754.018.16