Variable Pressure Support Ventilation

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The hypothesis of this study is that variable pressure support ventilation reduces the duration of mechanical ventilation to non-variable (convention-al) pressure support ventilation.

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

Summary

ID

NL-OMON38687

Source
ToetsingOnline

Brief title
ViPS

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
delayed weaning from mechanical ventilation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Mechanical ventilation, Noisy Ventilation, Variable Pressure Support Ventilation, Weaning

Outcome measures

Primary outcome

Weaning time defined as time from randomization to successful extubation.

Secondary outcome

* total time of mechanical ventilation

* length of stay in the ICU and in-hospital

* mortality

* lung function

* patient comfort

* organ failure

* need for noninvasive ventilation and reintubation;

* number of interventions of the ICU personal in the mechanical ventilator;

* variability of respiratory parameters of the breathing pattern

Study description

Background summary

PSV is the most commonly used form of assisted ventilation, but can result in reduced variability of VT as compared to spontaneous breathing in healthy subjects. A reduced level of variability of VT seems to be associated with delayed weaning from mechanical ventilation. Variable PSV is able to increase the variability of the respiratory pattern independent from the patient*s efforts, and has shown beneficial effects in terms of gas exchange, lung mechanics and diffuse alveolar damage and inflammation in animal models of acute lung injury. Furthermore, variable PSV decreased the work of breathing and improved comfort compared to conventional PSV in some patients evaluated so far.
Since variable PSV can reduce the mean pressure support, it may lead to a faster reduction of pressure support and, therefore, a shorter weaning period than conventional PSV.

Study objective

The hypothesis of this study is that variable pressure support ventilation reduces the duration of mechanical ventilation to non-variable (convention-al) pressure support ventilation.

Study design

International Multicenter Randomized Controlled Open Trial

Intervention

Variable PSV

Study burden and risks

Variable PSV is already commercially available in a mechanical ventilator and approved for clinical use. Thus, physicians are allowed to use variable PSV at their own discretion and several patients have been already ventilated with this new mode.
Compared to conventional PSV, variable PSV has been shown to improve gas exchange, respira-tory mechanics and breathing comfort, as well as to reduce inflammatory infiltrates and alveolar edema in experimental acute lung injury [11*14].
Preliminary results of the EVA Trial (Evaluation of Variable Pressure Support Ventilation in the Therapy of Acute Lung Injury; ClinicalTrials.gov Identifier: NCT00786292) showed that variable compared to conventional PSV did not increase discomfort or deteriorate the cardiopulmonary function in mechanically ventilated patients in the ICU. In fact, variable PSV importantly reduced the work of breathing and increased comfort in some patients.
Therefore, the burden and risks to patients resulting from the intervention are low. In fact, we hy-pothesize that patients assigned to variable PSV will be weaned faster from the mechanical venti-lator than those assigned to conventional PSV. Also, we expect that a considerable number of pa-tients under variable PSV will benefit in terms of reduced work of breathing and improved respira-tory comfort compared to non-variable (conventional) PSV.

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 * 18 years
* Duration of controlled mechanical ventilation * 24h
* Availability of a Infinity V500 ventilator (ready to use)
* Informed consent according to local regulations
* Temperature * 39 °C
* Hemoglobin * 6 g/dl
* PaO2/FIO2 * 150 mmHg with positive end-expiratory pressure (PEEP) *16 cmH2O
* Ability to breath spontaneously

Exclusion criteria

* Participation in another interventional trial within the last four weeks before enrollment in this trial
* Peripheral neurological disease associated with impairment of the res-piratory pump
* Muscular disease associated with impairment of the respiratory pump
* Instable thorax with paradoxical chest wall movement
* Planned surgery under general anesthesia within 72 hours
* Difficult airway/intubation
* Existing tracheotomy at ICU admission

* Expected survival < 72 hours
* Home mechanical ventilation or on chronic oxygen therapy
* Suspected pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2013
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	NCT01769053
CCMO	NL44074.018.13