PRotective VENTilation in Patients not Fulfilling the Consensus Definition for Moderate or Severe ARDS at Start of Ventilation * PReVENT, a Randomized Controlled Trial

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The present study aims at comparing a ventilation strategy with a lower tidal volume and a higher respiratory rate with ventilation using a higher tidal volume and a lower respiratory rate in ICU patients without moderate or severe ARDS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON44972

Source
ToetsingOnline

Brief title
PReVENT

Condition

- Respiratory disorders NEC

Synonym
Acute Lung Damage, Acute Respiratory Distress Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Intensive Care Volwassenen
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: high tidal volume, intensive care, low tidal volume, protective ventilation

Outcome measures

Primary outcome

The number of ventilator-free days at day 28 after ICU admission.

Secondary outcome

ICU and hospital length of stay (LOS) (follow up till day 90); incidence of

moderate or severe ARDS, pneumonia, atelectases, and pneumothorax; cumulative

use and duration of sedatives, and neuromuscular blocking agents; incidence of

ICU delirium, ICU acquired weakness, ICU mortality and hospital mortality,

90-day mortality.

Study description

Background summary

Mechanical ventilation is generally seen as an invasive but safe supportive strategy in critically ill patients with respiratory failure. However, there is unequivocal evidence from both experimental and clinical studies that ventilation has a strong potential to aggravate and even initiate injury to the lungs and the respiratory muscles. Ventilation results invariably in a pattern of ventral overstretching and dorsal collapse of lung tissue, which both play a role in development of so*called *ventilator*induced lung injury*. Ventilation is associated with respiratory muscle disuse and even misuse causing atrophy of diaphragmatic myofibers, which play a role in development of so*called *ventilator*induced diaphragm dysfunction*

The harmful effects of the traditional use of a higher tidal volume were not recognized until 2000 when the beneficial effects of ventilation with a lower

tidal volume in patients with moderate or severe ARDS (Acute Respiratory Distress Syndrome) were established in the landmark NHLBI ARDS Network trial. Currently, lung protective ventilation is considered standard of care for moderate or severe ARDS.

It is uncertain whether we should also use a lower tidal volume in patients without moderate or severe ARDS. One meta*analysis suggested that ventilation with a lower tidal volume benefits patients without ARDS. But there are several arguments against use of lower tidal volume ventilation in these patients: one argument is that a compensatory higher respiratory rate could increase sedation needs, which could increase the incidence of ICU delirium and ICU acquired weakness; others reasons are that this strategy could promote collapse of lung tissue; and the use of a higher respiratory rate could increase the risk of patient*ventilator asynchrony; more effort can induce more pendelluft and thereby lung injury, finally, an alleged side-effect of lower tidal volume ventilation is patient fatigue although there are no studies to support this. All of these could offset the beneficial effects of lower tidal volume ventilation as found in patients with moderate or severe ARDS. Thus, it is uncertain whether ventilation with lower tidal volume should be used routinely in all ICU patients. Consequently its use is not yet recommended in guidelines for ventilation of patients without ARDS resulting in remarkable and unwanted practice variation and continued use of higher tidal volumes

Study objective

The present study aims at comparing a ventilation strategy with a lower tidal volume and a higher respiratory rate with ventilation using a higher tidal volume and a lower respiratory rate in ICU patients without moderate or severe ARDS.

Study design

This is a national multicenter RCT in intubated and ventilated ICU patients without moderate or severe ARDS.

Intervention

Patients are randomly assigned in a 1:1 ratio to lower tidal volume ventilation (4-6 ml/kg predicted body weight) or ventilation with higher tidal volumes (8-10 ml/kg predicted body weight)

Study burden and risks

Burden and risks of the two ventilation strategies are uncertain. That's the goal of this study. Both strategies are currently used; there is no additional

risk for patients enrolled in this study compared to standard care.

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 intubation
- Within 1 hour of admission from the operation room or emergency room (if still intubated and ventilated), or within 1 hour of start of invasive ventilation in the ICU
- An expected duration of ventilation > 24 hours

Exclusion criteria

* Age less than 18 years
* Patients previously randomized in PReVENT
* Patients participating in other interventional trials
* Patients with moderate or severe ARDS (for Berlin consensus definition see table 1. APPENDIX I)
* Any session of ventilation > 12 hours directly preceding this ICU admission
* Patients with suspected or confirmed pregnancy
* Patients with increased and uncontrollable intracranial pressure (of *18 mmHg)
* Patients with GOLD classification III or IV chronic obstructive pulmonary disease (COPD)
* Patients with asthmatic status
* Patients with premorbid restrictive pulmonary disease (evidence of chronic interstitial infiltration on previous chest radiographs)
* Patients with new proven pulmonary thrombo*embolism
* Patients with any previous pneumectomy or lobectomy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	952
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2014

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2017
Application type:	Amendment
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	NCT02153294
CCMO	NL47013.018.14