Tidal ventilation distribution and patient-ventilator synchrony during Proportional Assist Ventilation with load-adjustable gain factors

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To compare the tidal volume distribution and other ventilator parameters between PAV+ and NAVA.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON43588

Source
ToetsingOnline

Brief title
Ventilation distribution during PAV+

Condition

- Respiratory tract infections

Synonym
respiratory distress, respiratory insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Intratidal Ventilation distribution, Neurally Adjusted Ventilatory Assist, Proportional Assist Ventilation

Outcome measures

Primary outcome

The main study endpoints are a shift of tidal impedance variation from the

ventral and central area of the lung towards central and dorsal area of the

lung, and stable PAV+ ventilation for 2-3 days.

Secondary outcome

The secondary objective is to assess the applicability of PAV+ in our current

ICU population.

Study description

Background summary

Proportional Assist Ventilation with load-adjusted gain factors (PAV+) is a new ventilation mode that delivers pressure proportional to the effort of the patient by measuring the resistance and compliance of the respiratory system trough the airway. It differs from Neurally Adjusted Ventilatory Assist (NAVA), another proportional mode, in that it is non-invasive. It is hypothesized that PAV+ will have similar effects on the tidal ventilation distribution than NAVA by promoting dorsal ventilation. This has not yet been objectified.

Study objective

To compare the tidal volume distribution and other ventilator parameters between PAV+ and NAVA.

Study design

Randomized intervention pilot study.

Intervention

Subjects are ventilated for 2-3 days with either NAVA (Group I) or PAV+ (Group II). Thereafter, the subject is ventilated using three levels of NAVA and three levels of PAV+ for 10 minutes each while more extensive respiratory mechanics measurements are performed.

Study burden and risks

The risk of this study is considered negligible. The burden for each a subject is considered mild. The benefit for the ICU population - i.e. a better insight in the physiology during PAV+ ventilation and a step towards non-invasive assist ventilation - is considered sufficient to justify the burden to the subjects.

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

Subject received mechanical ventilation with the Pressure Support mode and/or Neurally Adjusted Ventilatory Assist mode for at least 16 hours.

Exclusion criteria

Hemodynamic instability, respiratory distress during mechanical ventilation at inclusion, lack of spontaneous breathing effort.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-11-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Mechanical ventilator - Puritan Bennett 980 Ventilator System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-11-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL54587.078.15