Trend analyses Of Patient-Specific respiratory Physiologal INteractions for weaning decision support

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

Summary

ID

NL-OMON51035

Source
ToetsingOnline

Brief title
TOPSPIN

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Failure to reduce ventilatory support, Weaning failure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lung mechanics, Respiratory drive, Respiratory muscle function, Surface EMG

Outcome measures

Primary outcome

The primary outcome measure is the time in days between the first measurement, which takes place within 24 h of initiation of PS ventilation, and successful weaning (Twean). Successful weaning is defined as the patient being liberated from mechanical ventilation at least 48 h without requiring resumption of MV.

Secondary outcome

Secondary outcome measures are ICU (TICU) and hospital stay (Thospital).

Study description

Background summary

Approximately 30% of the patients receiving mechanical ventilation (MV) in intensive care units (ICUs) for more than two days have difficulties weaning, which is directly related to both serious complications of invasive MV, and poorer patient outcomes. The development of early prognostic factors that acknowledge the complexity of weaning failure might help to address this problem. However, the currently available parameters show no more than modest accuracies in predicting weaning outcomes. To address this problem, the authors propose an approach that takes the dynamically changing condition of ventilated patients into account; 1) acquire physiological data over the entire MV period in order to detect trends in patient status over time, and 2) use more state-of-the-art data analysis methods, preserving more context in the data and outcomes. Applied to the concept of breathing effort we propose to study the interactions between the physiological systems involved in the breathing; the neural respiratory drive and innervation, the respiratory muscle dynamics, and the respiratory system mechanics. This approach might provide more insight in the pathophysiological processes going on in a patient, and can thus be used to guide MV management decisions throughout the entire weaning process.

Study objective

The primary objective of this study is to investigate the relation between, on the one hand, 1) the balance between the respiratory system mechanics and muscle dynamics, and 2) the balance between the pressure support level and respiratory drive, and, on the other hand, the weaning duration in patients receiving prolonged mechanical ventilation.

Second, the effect of ventilatory support settings with respect to the optima in these physiological relations on the weaning duration, and the progression of these relations over the weaning duration are studied. Besides, the relations of various weaning strategies and aids (e.g. nasal high flow therapy, and inspiratory muscle training) with the course of the respiratory function are investigated.

Study design

This is a monocentre observational study.

Study burden and risks

The studied problem is linked to ICU patients, as they are ventilated for prolonged durations of time. This population is vulnerable by nature. However, the risks related to prolonged mechanical ventilation, and the current lack of good early prognostic factors, legitimate an observational study using a non-invasive measurement protocol, posing only limited discomfort to the patient, such that burdens and risks are minimised.

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

1. Informed consent,
2. aged 18 years or older,
3. receiving or expected to receive invasive MV for >48h,
4. ventilated in pressure support mode,
5. SpO2 >= 90% (13),
6. FiO2 <= 60% (13),
7. 0 >= Richmond Agitation Sedation Scale (RASS-score) >= -4

Exclusion criteria

1. a medical history of neurological disease that might affect the respiratory drive or neural conduction,
2. BMI > 30 kg/m^2,
3. pregnant,
4. moribund,
5. persistent pneumothorax.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-12-2021
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21854
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75951.091.21