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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21854

Source
NTR

Brief title
TOPSPIN

Health condition

Prolonged mechanical ventilation, muscle weakness, weaning, weaning failure

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

Weaning duration

Secondary outcome

ICU stay, hospital stay

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, we 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.
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 objective

Difficult to wean patients have a mismatch between optimal mechanical ventilation settings lung mechanics and respiratory muscle dynamics

Study design

Every other day from initiation of supported mechanical ventilation to successful weaning

Intervention

PEEP trials, PS trials, surface respiratory muscle EMG, airway occlusion pressures

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-08-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51035
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9654
CCMO	NL75951.091.21
OMON	NL-OMON51035

Study results