Oxygen Consumption (VO2), Effort, and Weaning in the Mechanically Ventilated Patient in the Intensive Care Unit (ICU)

Published: 10-11-2023
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The primary objective of the study is to investigate if the VO2, Pressure Time Product, Work of Breathing and transpulmonary Pressure Swings predict weaning failure or extubation failure after een succesfull SBT.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56162

Source
ToetsingOnline

Brief title
VO2 in the ICU

Condition

- Other condition

Synonym
Mechanically ventilated patients

Health condition

Beademde patienten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Mechanical ventilation, Oxygen consumption, Patient effort/work of breathing, Weaning

Outcome measures

Primary outcome

Weaning- or extubation failure (or success) after a successful SBT.

Furthermore, the differences between start and end of SBT and absolute values

of the following parameters: VO2, Pressure Swings, Work of Breathing, Pressure

Time Product, Rapid Shallow Breathing Index.

Secondary outcome

Not applicable

Study description

Background summary

Rationale: In patients who are mechanically ventilated for more than 72 hours weaning failure is a common issue. The Spontaneous breathing trial (SBT) is often done to assess if the patient can be extubated with a high chance of success. However, re-intubation rates are between 15 - 25 % after a successful SBT. The rapid shallow breathing index (RSBI) is an important parameter used in an SBT. Because the high incidence of extubation failure (re-intubation within 48 hours) a search for a better parameter than the RSBI is warranted. Using the measured end-tidal oxygen (etO2) of mechanically ventilated patients it is possible to calculate the VO2 , which is a measure of patient effort. The VO2 is a parameter with the potential to predict weaning success or failure, together with other parameters of patient effort like the work of breathing (WOB), pressure time product (PTP) and trans-pulmonary pressure swings. Therefore, we want to investigate if these parameters are associated with an

weaning success or failure.

Study objective

The primary objective of the study is to investigate if the VO2, Pressure Time Product, Work of Breathing and transpulmonary Pressure Swings predict weaning failure or extubation failure after een succesfull SBT.

Study design

A single center prospective cohort study performed on patients undergoing a weaning trial. Measurements will be performed the five minutes before a SBT, during, and the five minutes afterwards. The measurements will be derived from the Hamilton C6 mechanical ventilator and the Masimo ISA OR+. The SBT will be performed according to the ruling protocol (Appendix 15.1) in the LUMC. The investigation team will not make the decision to extubate and will not influence the medical team.

Study burden and risks

It is necessary to connect the Masimo ISA OR+ to the tubing of the respiratory system, for which the tubing must be disconnected from the ventilator for a short moment. This is a daily routine on the ICU per protocol (e.g. when changing the anti-bacterial filters attached to the ventilator) and happens without incidents. The collection of data has no influence on daily 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

18 years of age ore older
> 24 hours mechanically ventilated
- Eligible for a spontaneous breathing trial according to the clinical team
- Regular SBT ("Regulier SBT") according to the LUMC protocol
- Hemodynamically stable
- Esophageal Catheter in situ

Exclusion criteria

Known pregnancy
Severe COPD (Gold class IV) if it results in a non regular SBT according to the LUMC protocol.
Heart failure (LVEF < 30%) if it results in a non regular SBT according to the LUMC protocol.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2024
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL84568.058.23