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

Published: 06-05-2025
Last updated: 10-05-2025

Primary objective is to investigate if the sEMG signal derived from the SERA device has an association with weaning failure, defined as an unsuccessful SBT, or extubation failure, defined as the need for re-intubation for respiratory reasons within...

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

Summary

ID

NL-OMON57451

Source
ToetsingOnline

Brief title
eSERA

Condition

- Other condition

Synonym
Mechanical Ventilation, Weaning from mechanical ventilation

Health condition

Iedereen > 48 uur beademd voor welke reden dan ook

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: DEMCON Macawi respiratory systems, Best, The Netherlands,Samenwerking met DEMCON Macawi

Intervention

Keyword: Breathing Effort, Mechanical Ventilation, Surface electromyography of the diaphragm, Weaning

Outcome measures

Primary outcome

Magnitude of the electric signal (base level, or tonic level, maximum level,

AUC of the electric signal during contraction in inspiration and expiration,

differences between maximum and tonic levels), VO2, PTP, WOB, RSBI,

diaphragmatic pressure swing.

Secondary outcome

Secondary endpoints are the associations between the sEMG signals and the PTP,

WOB, Esophageal pressure swings, VO2.

Study description

Background summary

In patients mechanically ventilated for more than 72 hours weaning from the ventilator and successful extubation can be problematic. The spontaneous breathing trial (SBT) is a tool to predict successful extubation. However re-intubation withing 48 hours occurs in 15-20% of the patients after a successful SBT. The key parameter of the SBT is the rapid shallow breathing index (RSBI). Since the rate of extubation failure is still high the search for a better parameter than the RSBI is warranted.
Recently measurement of the surface electromyography of the respiratory muscles has become available with the Surface Electromyography Respiratory

Assist (SERA), which has been developed by Demcon-Macawi. The device is currently investigated in neonates in search of an apnea detection algorithm (protocol ID NL83937.000.23). The device gives an estimate of the magnitude of the electric activity of the diaphragm which has a good correlation with the force the diaphragm generates. It is known that the diaphragm is the key respiratory muscle and that dysfunction of the diaphragm has a strong association with weaning failure. We think that this signal could be of great value in detecting weaning and extubation failure therefore we want to investigate if the sEMG signal derived from the SERA device has an association with weaning failure, defined as an unsuccessful SBT, or extubation failure, defined as the need for re-intubation for respiratory reasons within 48 hours after a successful SBT and subsequent extubation.

Study objective

Primary objective is to investigate if the sEMG signal derived from the SERA device has an association with weaning failure, defined as an unsuccessful SBT, or extubation failure, defined as the need for re-intubation for respiratory reasons within 48 hours after a successful SBT and subsequent extubation. Secondary objectives are to investigate if the sEMG signal has an association with other measurements of effort (pressure time product (PTP), Work of breathing (WOB), Transpulmonary pressure swings, oesophageal pressure swings, and oxygen consumption

Study design

A single center prospective cohort feasibility/pilot study performed on patients undergoing a spontaneous breathing trial. Measurements will commence 10 minutes before the planned SBT, will continue during the SBT until 10 minutes after the termination of the SBT. Measurement data will be derived from the SERA, the mechanical ventilator (Hamilton C6), and the Masimo ISA OR+. The SBT will done according to the ruling protocol.

Study burden and risks

The collection of data will not affect the standard of care. Therefore, the patient*s risk is negligible and the burden is minimal.

Contacts

Public
Leids Universitair Medisch Centrum

Albinsudreef 2

Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinsudreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Mechanically ventilated for 48 hours or more
- 18 years of age or older
- Esophageal catheter in situ (standard of care)
- Eligible for an SBT in the near future according to the LUMC SBT protocol currently valid
- Informed consent from the patient obtained before admission to the ICU, e.g. in case of planned surgery, or obtained from te patient on the ICU if the patient is able to give consent and has not given consent previously.

Exclusion criteria

- Severe cardiac failure NYHA class IV without mechanical support (LVAD or Impella)
- COPD Gold IV
- Pregnancy
- ECMO

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2025
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	surface EMG device
Registration:	No

Ethics review

Approved WMO

Date:	06-05-2025
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	NL86876.000.24