Surface electromyography of the diaphragm on the intensive care unit: A pilot study

Published: 22-08-2014
Last updated: 15-05-2024

In this pilot study we aim to investigate the additional value of sEMG signals of respiratory muscles during ICU admission in adults.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40797

Source
ToetsingOnline

Brief title
SEDICU

Condition

- Neuromuscular disorders

Synonym
diaphragm weakness; intensive care unit acquired weakness

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diaphragm, ICU, Mechanical ventilation, surface elektromyography

Outcome measures

Primary outcome

* Feasibility

* Correlation of transcutaneous sEMG of the diaphragm with EAdi signal of

NAVA catheter.

* Correlation of transcutaneous sEMG of the diaphragm with airway pressure and

flow to detect patient * ventilator dyssynchrony

* Changes in sEMG signals during increased physical activity

* Correlation of sEMG fatigue parameters with clinical parameters of fatigue

during weaning from mechanical ventilation

Secondary outcome

* Weaning failure parameters

* Patient experience of respiratory fatigue and nurses* estimate of respiratory

fatigue of the patient

Study description

Background summary

Patients on the intensive care unit often need mechanical ventilation. In the last few years it has become clear that mechanical ventilation is harmful for the diaphragm. This leads to diaphragmatic dysfunction and weakness. The electrical activity of the diaphragm (EAdi) can be detected by three electromyography (EMG) methods: transcutaneous EMG, intramuscular EMG and trans esophageal EMG. Transcutaneous electromyography, also called surface electromyography (sEMG), is the least invasive method. Optimized monitoring to specifically monitor fatigue of the respiratory muscles, might accelerate the

weaning process and diminish the length of mechanical ventilation and ICU stay.

Study objective

In this pilot study we aim to investigate the additional value of sEMG signals of respiratory muscles during ICU admission in adults.

Study design

This is a single center prospective observational cohort pilot study.

Study burden and risks

sEMg is a non-invasive, painless, harmless investigation, which can be performed at the bedside at the ICU, thus having a negligible risk and burden for the patient. Patients will not directly benefit from participation in this study. However, sEMG monitoring of the diaphragm and external intercostal muscles may benefit patients in the future. Collection of general data from (electronic) medical records does not affect the patient. Prolonged mechanical ventilation and weaning is intimately related to the ICU environment. Therefore, substitution of this patient group is not possible

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Informed consent
Age 18 years
Expected duration of mechanical ventilation for * 48 hours

Exclusion criteria

(Suspected) neuromuscular disease (other than ICU-AW) or cervical spinal cord injury
Known phrenic nerve injury
Contraindication for electrode placement (e.g. severe skin infection at electrode site)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2014
Enrollment:	120

Type:	Actual

Ethics review

Approved WMO Date:	22-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 20779
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50006.018.14
OMON	NL-OMON20779