Electrical activity of the diaphragm as predictor of detubation failiure

Published: 27-03-2017
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To determine the impact of detubation on changes in electrical activity of the diaphragm in adults, children and neonates.

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

Summary

ID

NL-OMON50367

Source
ToetsingOnline

Brief title
Detubation faulire (BRAHMS)

Condition

- Neonatal respiratory disorders

Synonym
Detubation failure, mechanical ventilation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Detubation failure, Electromyography

Outcome measures

Primary outcome

Changes in electrical activity of the diaphragm before and after detubation.

Secondary outcome

The relation between changes in electrical avtivity of the diaphragm and

detubation failure.

Study description

Background summary

The provision of invasive respiratory support with an endotracheal tube (ET) is a core feature of intensive care medicine. Removal of the ET is the last step in the weaning process. Detubation is of great importance because failure of detubation is associated with an increased duration of mechanical ventilation, prolonged stay on an intensive care unit (ICU), the need of a tracheostomy, higher mortality rate and higher costs. Various weaning predictors have been investigated to enable the likelihood of a successful weaning to be assessed as early and accurate as possible. All these predictors have limited utility in the predicting the success of detubation.
Studies show that transcutaneous electromyography of the diaphragm (dEMG) is a reliable basic cardiorespiratory monitor and it is capable to detect changes in diaphragmatic activity after an intervention. This information might be useful when weaning a patient from the mechanical ventilation. The aim of this study is to compare patients successfully separated from the ventilator and the ET and those who failed, in terms of various dEMG-derived parameters, and to assess the putative use of such parameters for outcome prediction.

Study objective

To determine the impact of detubation on changes in electrical activity of the diaphragm in adults, children and neonates.

Study design

Prospective observational cohort study.

Electrical activity of the diaphragm is measured by dEMG before and after

separation of the mechanical ventilator and ET.

Study burden and risks

The study population will not benefit from participating in this research. This study will expand our knowledge on detubation failure what will benefit future care for these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Mechanical ventilation via an endotracheal tube for at least 24 hours, whatever the underlying disease and the reason for ventilatory assistance
- The decision to detubate the patient is made by the physician in charge of the patient.
- The attending phycician considers the patient to be vulnerable to participate in the study
- Written informed consent from the patient or legal representative(s)

Exclusion criteria

- those for whom life support will be withheld or withdrawn will not be included in the study

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):	16-05-2017
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2017
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL58426.018.16