SERA - Surface Electromyography for Respiration and Apnea monitoring in preterm infants

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

Summary

ID

NL-OMON56138

Source
ToetsingOnline

Brief title
SERA

Condition

- Neonatal respiratory disorders

Synonym
Apnea of Prematurity, breathing pauses

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Demcon - Macawi respiratory systems

Intervention

Keyword: apnea monitoring, diaphragm, electromyography, infants

Outcome measures

Primary outcome

Sensitivity/Specificity of the developed apnoea detection algorithm (based on the measurements made), relative to the gold standard. The standard here concerns the clinical evaluation, with the clinical expert himself determining whether and if so what type of apnoea is present.

Secondary outcome

Sensitivity/specificity for distinguishing the different types of apnoea (central, obstructive, mixed). Moreover,ability to use dEMG data to observe changes in diaphragm activity over time, among others during changes in respiratory support, will be studied. In addition, information on the functionality of the SERA will be collected using the measurement signal itself (i.e. to observe the occurrence of a loss of Bluetooth connection and the amount of time with an electrode off) and using a short survey to acquire the clinical opinion of the treating nurses considering the ease-of-use of the SERA device.

Study description

Background summary

A large proportion of preterm infants admitted to the Neonatology ICU have so-called apnoeas, breathing stops that originate from the underdevelopment of the respiratory centre. This is therefore also called Apnoea of Prematurity (AOP). The number of these incidents is initially low, increases in the second

week of life, then stabilises in the 3rd/4th week of life and the number of incidents decreases again. Despite the fact that in the majority of children, apnoeas disappear with time, detecting them and treating them, does matter. During an apnoea, oxygen levels in the blood may drop and the heart rate may also react to this. Research shows that these moments of hypoxia (too low amount of oxygen) can be detrimental to child development in the long term. However, accurate apnoea detection and classification has so far proved difficult. This makes treatment reactive and less proactive. There is still much scope for improving patient monitoring to thereby reduce the number of apnoeas and their negative effects.
Measurements of the muscle activity of the diaphragm provide direct insight in respiration and could therefore be used to detect and classify apnea. The SERA device can measure the diaphragm activity and is the successor of the Dipha-16 device, as the Dipha-16 is no longer for sale and is considered end-of-life.
The SERA is identical to the Dipha-16 with respect to the signal acquisition and amplification. The SERA contains new firmware and is therefore different in terms of signal analysis. The to be developed apnea detection algorithm in this study is aimed to be integrated within the SERA device. Therefore, the SERA hardware, combined with the software algorithm are considered the investigational product.

Study objective

The aim of this study is to use diaphragmatic muscle activity measurements in premature neonates to develop an algorithm that can quickly identify that the patient has apnoea and then classify it by type (obstructive, central or mixed). This could provide more insight into the patient's respiratory condition and then guide treatment.

Study design

It is a mono-centre prospective observational cohort study, in two phases.

Intervention

Within this study the only intervention is the measurement of diaphragm activity with three surface electrodes for to 8 hours, in order to record several apnea periods.

Study burden and risks

This study uses only non-invasive measurement instruments and does not change anything about the standard care the patient receives. Although the measurements will take several hours, the burden on the patient is minimal. In addition, the electromyography technique used has been used in research for

many years, with no adverse effects on the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

- Gestational age (GA) between 26 and 32 weeks
- Receiving non-invasive respiratory support in the form of:
o High-flow nasal cannula (HFNC)
o Nasal continuous positive pressure (nCPAP)
o Non-invasive Positive Pressure Ventilation (nIPPV)
- Parental/guardian informed consent

Exclusion criteria

- Congenital anomalies that prevent the execution of a dEMG measurement
- (indication for) Abdominal surgery that prevents the execution of a dEMG measurement
- End of life decision

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-09-2023
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	SERA
Registration:	No

Ethics review

Approved WMO

Date:	30-08-2023
Application type:	First submission
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	NL83937.000.23