Improving respiratory monitoring by directly capturing the electrical activity of the diaphragm

Published: 29-05-2020
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To collect reference data of dEMG in neonates to use for testing the Bambi Belt B.V. algorithm which is under development.

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

Summary

ID

NL-OMON49239

Source
ToetsingOnline

Brief title
Explorative study for algorithm testing JBZ

Condition

- Other condition

Synonym
Cardio-respiratory status, premature infants

Health condition

Monitoring van ademhalingsfrequentie (en hartfrequentie) in neonaten

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Bambi Belt B.V.

Intervention

Keyword: Diaphragmatic EMG, Monitoring, Preterm infants

Outcome measures

Primary outcome

To collect sufficient reference data of dEMG in neonates, in a representative

population and for specific routine caregiving scenarios, to use for testing

and optimizaton of the Bambi Belt B.V. algorithm.

Secondary outcome

Not applicable

Study description

Background summary

In preterm infants, respiration is currently measured using chest impedance (CI). Whilst proven to be a useful method, CI has important limitations, such as inaccuracies in monitoring respiration due to cardiac interference and nonbreathing-related chest wall movement. Respiration can also be determined by directly measuring the electrical activity (electromyography) of the diaphragm (dEMG). Bambi Belt B.V., a Dutch med-tech company, aims to market a product that measures dEMG in neonates specifically. To assess the functioning of this new device and improve the algorithm used in this device, neonatal reference data including dEMG data has to be obtained with a CE-certified medical device, such as the Delsys Trigno Wireless Biofeedback System.

Study objective

To collect reference data of dEMG in neonates to use for testing the Bambi Belt B.V. algorithm which is under development.

Study design

Observational within-subject explorative study.

Study burden and risks

The results of this study will have no direct benefit to the patient because the study is observational. The dEMG recordings are not available for guiding care. This is a non-invasive, observational study in which infants will wear an additional monitoring device with minimal risks. This study needs to be conducted in infants, since this is the population of intended use for the new monitoring device.

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
Den Bosch 5223GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
Den Bosch 5223GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Gestational age 26 - 42 weeks
Written parental informed consent

Exclusion criteria

-Patients requiring defibrillation. The device should be removed prior to start of defibrillation -Patients with implanted electronic devices of any kind, including cardiac pace-makers or similar assistive devices, electronic infusion pumps and implanted stimulators
-Patients with irritated skin or open wounds or with allergies to Silver . In case skin irritation or discomfort occurs, use of device must be discontinued.
-Patients requiring diagnostic imaging (X-thorax, MRI, cardiac ultrasonography) during the study
-Unsuitability for an informed consent conversation; e.g. timewise or attention-wise too much of a burden for parents
-Patients with parents who do not speak and/or read the native language or English

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):	16-06-2020
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Delsys Trigno Wireless Biofeedback System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-05-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-06-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL73458.028.20

Study results

Date completed:	21-01-2021
Results posted:	13-08-2021
Actual enrolment:	35

First publication
13-08-2021

URL result

URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File