Feasibility of wireless cardio-respiratory monitoring with a belt in preterm infants

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The objective of this explorative study is to determine the feasibility of measuring dEMG with a belt in preterm and term born infants during routine caregiving. Feasibility is confirmed when heart rate and respiratory rate reach a predefined level...

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

Summary

ID

NL-OMON49716

Source
ToetsingOnline

Brief title
Wireless monitoring with a belt in preterm infants

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: Academisch Medisch Centrum
Source(s) of monetary or material Support: Bambi Medical B.V.

Intervention

Keyword: Diaphragmatic EMG, Monitoring, Preterm infants, Wireless

Outcome measures

Primary outcome

The feasibility of measuring dEMG using a belt based on acceptability of the

level of agreement with CI

Secondary outcome

Skin condition when wearing the belt as rated by nurses

Study description

Background summary

In preterm infants, heart rate, ECG and respiration monitoring is performed using adhesive electrodes. These electrodes can damage the skin, and the wires they are attached to impede parent-infant interaction. These problems may be solved by a non-adhesive, wireless belt able to perform cardiorespiratory monitoring in neonates. Such a belt is currently being developed by Bambi Medical B.V. The belt uses the technique of diaphragmatic electromyography (dEMG) to accomplish cardiorespiratory monitoring, a recently introduced (via adhesive electrodes) monitoring technique in the neonatal intensive care unit (NICU), because it has the potential to improve respiratory and apnea monitoring over traditional chest impedance (CI) monitoring, by providing direct insight in breathing effort of the infant. dEMG monitoring might guide the optimal choice of respiratory support. It can provide both a heart rate, ECG, and respiratory rate and as such this technique could potentially replace CI monitoring. However, to date the feasibility of obtaining a dEMG signal with a belt has not been studied.

Study objective

The objective of this explorative study is to determine the feasibility of

measuring dEMG with a belt in preterm and term born infants during routine caregiving. Feasibility is confirmed when heart rate and respiratory rate reach a predefined level of agreement between the wireless belt and standard electrode monitoring.

Study design

Prospective observational study design

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 a minimal risk of skin irritation. This study needs to be conducted in infants, since this is the population of intended use for the new monitoring device.

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
Children (2-11 years)

Inclusion criteria

Gestational age 26 * 42 weeks
Written parental informed consent

Exclusion criteria

Chest skin lesions preventing placement of electrode belt
Congenital anomalies

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):	14-09-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Bambi Belt
Registration:	No

Ethics review

Approved WMO Date:	05-03-2020
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	NL72488.018.20