Multi-center non-inferiority study of the monitoring performance of the BAMBI BELT; a wireless device measuring neonatal heart rate, ECG and respiration based on diaphragmatic electromyography

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To establish equivalence (non-inferiority) between monitoring performance of the Bambi Belt and the currently used cardio-respiratory monitoring device. The Bambi Belt is a potentially more patient friendly, wireless cardio-respiratory monitoring...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON50960

Source
ToetsingOnline

Brief title
Monitoring performance of the Bambi belt

Condition

- Neonatal and perinatal conditions

Synonym
cardio-respiratory instability, Prematurity

Research involving

Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Bambi Medical B.V.,Bambi Medical B.V. betaalt de benodigde materialen en een bijdrage voor de tijdsbesteding

Intervention

Keyword: Cardio-respiratory, Monitoring, Neonates, Wireless

Outcome measures

Primary outcome

The primary endpoints are a) equivalence of heart rate monitoring (as measured by i) second-to-second correlation and level of agreement, and ii) bradycardia and tachycardia sensitivity and positive predictive value (PPV)) and b) safety (as measured by data loss and pre-defined relevant adverse events and adverse device effects).

Secondary outcome

Secondary endpoints are equivalence of respiratory monitoring, and the visual interpretability of waveforms (ECG and respiration waveforms) as rated by independent, blinded experts.

Study description

Background summary

In sick or prematurely born neonates, monitoring of the heart rate, ECG, and respiration is routinely performed using adhesive electrodes that obtain the electrical activity of the heart and chest impedance. Especially in neonatal intensive care units (NICUs), where all infants require monitoring, alternative monitoring methods are desired to replace such obtrusive adhesive electrodes, attached to hindering wires.

Study objective

To establish equivalence (non-inferiority) between monitoring performance of the Bambi Belt and the currently used cardio-respiratory monitoring device. The Bambi Belt is a potentially more patient friendly, wireless cardio-respiratory monitoring device measuring diaphragmatic electromyography (dEMG).

Study design

Multicenter study in the Máxima Medical Center and Amsterdam Medical Center. The study is of an observational within-subject design. Subjects will be monitored with the Bambi Belt for 24 hours, in addition to standard monitoring.

Study burden and risks

Non-invasive, observational study in which infants have to wear an additional monitoring device. Although unexpected, the risk of skin irritation due to this device cannot be ruled out. There are no benefits for participating infants. This study might demonstrate substantial benefits for a similar population in the near future. These potential benefits outweigh the minimal risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* Admitted to a participating NICU
* Being routinely monitored using adhesive electrodes for cardiorespiratory monitoring
* Written parental informed consent
* Of a post-menstrual age (PMA) cohort that is not already fully represented in the study (to include representative numbers, inclusion is performed based on three cohorts, PMA < 28 weeks, PMA 28-37 weeks, PMA > 37 weeks)

Exclusion criteria

* Chest skin lesions preventing placement of electrode belt, since the intended use of the belt is for intact skin.
* Congenital anomalies preventing placement of electrode belt
* (Effects of) surgery preventing or hindering belt placement, such as a laparotomy or stoma

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):	15-07-2021
Enrollment:	39

Type:	Actual

Medical products/devices used

Generic name:	BAMBI BELT
Registration:	No

Ethics review

Approved WMO Date:	21-05-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL77436.015.21