Monitoring performance of a wireless belt for neonates

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23933

Source
NTR

Brief title
TBA

Health condition

Prematurity

Sponsors and support

Primary sponsor: Máxima Medical Center (participating center: Amsterdam Medical Center)
Source(s) of monetary or material Support: Bambi Medical B.V.

Intervention

Outcome measures

Primary outcome

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. In this study, the aim is to establish non-inferiority of the monitoring performance of an alternative, wireless monitoring device.

Study objective

The monitoring performance of a wireless alternative for cardiorespiratory monitoring in neonates is equivalent (non-inferior) compared to routine monitoring with adhesive electrodes.

Study design

Additional monitoring with the belt is performed for 24 hours continuously. The study ends after these 24 hours, there is no follow up.

Intervention

Additional (non-invasive) monitoring with a wireless, wearable, biocompatibile belt

Contacts

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Eligibility criteria

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 that is not already fully represented in the study (to include a representative sample, inclusion is performed in three cohorts, <28 weeks, between 28-37 weeks, > 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-06-2021
Enrollment:	39

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL9480
Other	METC MMC : W21.042

Study results