

Wireless unobtrusive cardiorespiratory monitoring directly after birth

Published: 22-02-2023

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Demonstrate the suitability of cardiorespiratory monitoring directly after birth using a novel, wireless, non-adhesive device.

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

Summary

ID

NL-OMON53787

Source

ToetsingOnline

Brief title

Cardiorespiratory monitoring directly after birth

Condition

- Other condition

Synonym

Fetal to neonatal transition, neonatal physiology

Health condition

neonatale monitoring

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Bambi Medical B.V.,Bambi Medical levert de

materialen;JBZ levert in-kind uren

Intervention

Keyword: Cardiorespiratory, Monitoring, Neonates, Wireless

Outcome measures

Primary outcome

time to display HR after belt application.

Secondary outcome

ease of belt application, continuity and reliability of the monitor data throughout the monitored period, and workflow and parent-infant interaction in relation to the device throughout the monitored period as based on a limited number of questions.

Study description

Background summary

The golden standard for HR measurement is HR obtained through adhesive ECG electrodes. However, adhesive ECG electrodes have some disadvantages. They are not suitable for use directly after birth (on a wet neonate), and the adhesives can cause skin damage while the wires hinder parent-infant interaction and staff workflow. Novel devices may provide a more suitable alternative for cardiorespiratory monitoring directly after birth.

Study objective

Demonstrate the suitability of cardiorespiratory monitoring directly after birth using a novel, wireless, non-adhesive device.

Study design

Prospective study investigating the suitability of wireless cardiorespiratory monitoring with a wearable belt applied to unprepared skin directly after birth. The study consists of a feasibility phase and a consecutive validation

phase (if monitoring on the unprepared skin appears feasible).

Study burden and risks

Non-invasive study in which newborn infants wear a new wireless cardiorespiratory monitoring device directly after birth. During the study, the monitor is turned to face the wall, and alarms (audible and visible) are disabled, so obtained data are only analyzed retrospectively but not used during the study. Although unexpected, the risk of skin irritation due to the device cannot be ruled out whilst there are no potential benefits to the participants. However, this study might demonstrate substantial benefits for a similar population in the near future. Based on structured risk assessment, the potential benefits therefore outweigh the minimal risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Newborns

Inclusion criteria

- The baby (at the moment of consent still a fetus) will be born in the Jeroen Bosch Hospital
- Without (prenatal) indication for cardiorespiratory monitoring
- With prenatal written informed consent from parents to participate in the study (in Dutch)

Exclusion criteria

- Chest skin lesions at the site of the belt (the belt is intended for intact skin).
- Congenital anomalies preventing placement of wearable belt, e.g. Siamese twins

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): 15-03-2023

Enrollment: 60

Type: Actual

Medical products/devices used

Generic name: Bambi belt

Registration: No

Ethics review

Approved WMO	
Date:	22-02-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	06-05-2024
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	NL82020.028.22

Study results

Date completed:	11-07-2024
Results posted:	16-01-2025
Actual enrolment:	54

First publication

16-01-2025