Heart rate registration in neonates using a PPG-integrated cap

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Primary Objective: To assess the agreement between the heart rate assessed with a dedicated cap with integrated PPG-leads and standard ECG monitoring using regular neonatal thoracic electrodes as reference technique.Secondary objectives:Does...

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

Summary

ID

NL-OMON49842

Source
ToetsingOnline

Brief title
Well hatted

Condition

- Neonatal and perinatal conditions

Synonym
sick newborns/neonates

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Heart rate registration, Neonate, Photo plethysmography

Outcome measures

Primary outcome

The main study parameter is the heart rate. The primary endpoint is the agreement of heart rate monitoring between innovative PPG technology integrated in a cap and standard heart rate monitoring using regular thoracic ECG electrodes.

Secondary outcome

• Time interval between birth and the first adequate registration of the heart rate

• Time interval between application of monitoring device and adequate registration of the heart rate

• Feasibility, accuracy and precision when the innovative cap is used in an infant who is supported by invasive or non-invasive respiratory support (e.g. nCPAP, NiPPV, HFO-V).

Study description

Background summary

About 10% of newborns require some assistance during transition after birth; about 1% are in need of more extensive resuscitation (1). The initial postnatal evaluation includes the assessment of the heart rate.
Studies have shown that clinicians have trouble measuring the heart rate with a stethoscope (1,2) and that pulse oximetry underestimate the HR compared with ECG-electrodes during the first 7 minutes of life (3). The gold standard reference technology for HR-monitoring is ECG. But some studies have shown that even ECG may take up to 82 seconds before the heart rate can be accurately

assessed (4).

Moreover, almost all infants admitted to the neonatal ward require monitoring of their vital signs. The heart rate of those infants who are especially vulnerable, the extremely preterm infants (gestational age < 26 weeks), cannot be monitored via conventional ECG-electrodes due to the sensitivity of their skin. They are however most at risk for bradycardia secondary to apneas, related to their immaturity. Currently only pulse oximetry is used for heart rate monitoring in these extreme preterm infants, unless an (umbilical) arterial catheter is in place. Which can measure the HR and blood pressure For neonates born at a gestational age of 26 weeks or higher, ECG-monitoring using regular thoracic neonatal electrodes is standard practise.
Use of a cap with integrated PPG leads could help clinicians assess the heart frequency to determine when resuscitation should be initiated or ceased without damaging the skin. It could also help monitor extremely preterm infants more closely in the NICU.
Since the cap has wireless leads, it will not interfere with Kangaroo care.

Study objective

Primary Objective:
To assess the agreement between the heart rate assessed with a dedicated cap with integrated PPG-leads and standard ECG monitoring using regular neonatal thoracic electrodes as reference technique.

Secondary objectives:
Does simultaneous use of nCPAP or HFO-V influence the accuracy of heart rate monitoring using the dedicated cap?
How quickly can a reliable heart rate be obtained in the delivery room?

Study design

Single center, prospective comparative study in the neonatal ward of the Radboudumc Amalia children*s hospital.

Study burden and risks

All neonates will receive treatment according to our current protocol of measuring heart rate.
The burden of participation will be low because it is already standard practice to put on a cap after birth.
The burden for our study population will consist of removing the PPG-sensor immediately after data acquisition, the cap itself can remain on the neonate's head.
The cap is CE certified for all newborn babies including extremely premature neonates.

No adverse effects have been described in earlier studies. Studies which have also included premature babies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Gestational age
a. group 1: neonates born at a gestational age of >=32 weeks with standard cardiorespiratory monitoring.
b. group 2: neonates born at a gestational age of >=26 weeks with or without

nCPAP (Nasal continuous positive airway pressure).
c. Phase 2/ group 3: Extreme preterm infants born at a gestational age between 24 and 26 weeks.
d. Group 4: Term and preterm newborn infants at birth
• Informed consent from parents or caregivers

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• nCPAP (group 1)
• Cerebral Function Monitoring (group 1, 2 and 3)
• Peripheral intravenous catheter located on the skull (group 1, 2 and 3)
• Skin lesions on the skull
• Life-threatening congenital defects

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-09-2021
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	photo plethysmography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72793.091.20