Comparing pulse rate measurement in newborns using conventional and dry electrode ECG monitors

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To determine the accuracy of the *NeoBeat* device against gold standard measurements obtained by an ECG monitor with disposable (gel) electrodes and against pulse measured preductally as derived by pulse-oximeter.

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

Summary

ID

NL-OMON48339

Source
ToetsingOnline

Brief title
RECON

Condition

- Neonatal and perinatal conditions
- Neonatal respiratory disorders

Synonym
hart rate monitoring, neonatal transition

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ECG, Neonate, Pulse oximetry, Transition

Outcome measures

Primary outcome

Correlation of all pulse rate measurements of the Neobeat, ECG monitor and pulse oximetry device:

All continuous data will be compared during the first 10 minutes after birth.

The relationship between the three devices will be evaluated using Bland-Altman bias analysis; the difference between the measurements will be plotted against their average. The sensitivity, specificity, positive predictive values, and negative predictive values of measurements collected using the Neobeat, ECG and pulse oximetry for detecting HRECG <100 bpm will be calculated.

Secondary outcome

1) Correlation between signals of the three monitoring devices over time.

All continuous data will be compared during the first 10 minutes after birth.

Data will be plotted over time and averaged for 30 second intervals and plotted for each different monitoring device. Data will be compared using an Anova for multiple continuous normally distributed values

2) Duration from application until a reliable signal is acquired.

The time until the first reliable signal is acquired is averaged for all three devices and compared using an ANOVA for normally distributed values. The Friedmans* test will be used for non-normally distributed data.

Study description

Background summary

The majority of neonates undergo neonatal transition at birth without any problems, however around 5% of term infants and 60% of preterm infants receive some form of respiratory support. According to international guidelines, the necessity for support during neonatal resuscitation is assessed using 2 objectively measured parameters: heart rate and oxygen saturation. The evaluation of the clinical condition of the infant depends on accurate measurement of heart rate. According to the guidelines positive pressure ventilation should be commenced below a heart rate of 100 beats per minute and below 60 beats per minute chest compressions should be commenced.

Heart rate can be measured either by clinically assessing pulse, but this is unreliable. Other more reliable methods are measuring pulse on one of the extremities using a pulse oximeter or by using electrocardiography (ECG) to measure the electrical activity of the heart. The overall difference between pulse measured by ECG and pulse measured by pulse-oximetry (PO) is small (only 4 beats difference on average). However, at the start of transition shortly after birth measurement differences can be up to 35 beats per minute, which could lead to unnecessary interventions.

ECG measurements are the golden standard for heart rate measurements in adults and neonates. They are fast and will provide a reliable measurement within 2 seconds after application. *Neobeat*, is a novel arch-shaped device for measuring heart rate during neonatal resuscitation using dry-electrode ECG. It can quick and easily be applied by placing it around the abdomen or thorax of the neonate and does not need any disposable electrodes, making it ideal for low-resource settings. Only one study has proven that the Neobeat is a fast and safe device to use during transition. There is no data available in which it has been compared with other devices which are commonly used to measure heart rate.
With this study we would like to investigate the accuracy of this device by determining 1) correlation of all pulse rate measurements of the *Neobeat*, standard ECG monitor and pulse-oximeter. 2) Correlation between signals of the three monitoring devices over time. 3) Duration from application of the *NeoBeat* until a reliable signal is acquired.

Study objective

To determine the accuracy of the *NeoBeat* device against gold standard measurements obtained by an ECG monitor with disposable (gel) electrodes and against pulse measured preductally as derived by pulse-oximeter.

Study design

A prospective observational study.

Study burden and risks

Burden for patients:
Measuring of vital parameters (using ECG and PO) at birth is a standard procedure and will always be used when deemed necessary by the caregiver during transition at birth. The *NeoBeat* is a device which fits around the thorax of an infant and does not hamper neonatal transition as it will not obstruct breathing. Although chest compressions could still be administered when the device is present the device will be removed if chest compressions are necessary to make sure it does not interfere with treatment.

Risks and benefits:
Both benefits and risks are limitedThere are no benefits or risks in this study as newborn infants are included and regular monitoring is used according to (inter)national guidelines and no clinical decisions will be based upon the extra data collected using the *Neobeat* device.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants born at a gestational age at least 32 weeks who are evaluated on the resuscitation table during neonatal transition at birth. The estimated birth weight must be at least 1500 grams

Exclusion criteria

Infants that have congenital abnormalities of the thorax, an estimated foetal weight of less than 1500 grams, or are withheld life support at birth

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Newborn Heart Rate Meter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-01-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL71052.058.19