Umbilical cord oximetry for measuring heart rate in neonatates at birth: a feasibility study

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To determine the feasibility of umbilical PO for HR measurements after cord clamping in infants needing stabilization at birth and to compare this with standard PO on the right hand.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49437

Source
ToetsingOnline

Brief title
U-COUNT study

Condition

- Neonatal respiratory disorders

Synonym
neonatal changes from intrauterine to extrauterine life, neonatal transition

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: vidi beurs

Intervention

Keyword: heart rate, neonatal resuscitation, pulse-oximetry, Umbilical cord

Outcome measures

Primary outcome

The time needed to obtain an accurate HR signal after sensor placement. An accurate signal will be defined as a stable display of HR with a good plethysmograph signal, without *low signal* alarms.

Secondary outcome

* Proportion of infants in whom the PO sensor can successfully be placed on the umbilical cord.

* Proportion of infants with an accurate HR signal.

* HR (umbilical and right hand) at 2 second intervals during the first 10 min after birth.

Study description

Background summary

Approximately 10% of all newborn infants fail to adapt from fetal to neonatal life after birth, and require additional respiratory support for cardiopulmonary stabilization. At birth, heart rate is the most important indicator used to evaluate the clinical condition of newborns. Subsequently, adequate monitoring of this parameter is needed to successfully guide interventions needed for stabilization.
The standard procedure for evaluating heart rate in newborn infants is pulse oximetry measured at the right hand (pre-ductal). However, several studies have shown that pulse oximetry measurements obtained at the right hand are often inaccurate in the first minutes. Umbilical pulse oximetry might lead to faster and more accurate heart rate measurements, but this has so far not been tested. Umbilical pulse oximetry will only be clinically useful when accurate heart rate measurements can be obtained faster than pulse oximetry on the right hand. We hypothesize that it is feasible to measure heart rate using umbilical pulse

oximetry after cord clamping in newborns needing stabilization at birth, and that accurate heart rate measurements will be obtained faster when compared to measurements obtained at the right hand.

Study objective

To determine the feasibility of umbilical PO for HR measurements after cord clamping in infants needing stabilization at birth and to compare this with standard PO on the right hand.

Study design

Prospective observational study.

Study burden and risks

The are no risks associated with participation in this study. The sensors used in this study are specifically designed for preterm born infants and will be gently wrapped around the base of the umbilicus (where the umbilicus is still covered with skin epithelial). Local NICU protocol states that sensors should be renewed and relocated every four hours. Sensors in this study will only be placed during a maximum time of 10 minutes, therefore we do not expect any risks concerning the use of this device.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants born between 26-42 weeks gestational age where stabilisation at birth is anticipated.

Exclusion criteria

Infants participating in the ABC3 trial, who are randomized to physiological based cord clamping and are stabilised on the Concord resuscitation table.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2020
Enrollment:	18
Type:	Actual

Medical products/devices used

Generic name:	Masimo Radical-7 pulse oximeter
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	NL72220.058.19

Study results

Date completed:	01-07-2020
Actual enrolment:	18