Umbilical oximetry during the neonatal transition: a feasibility study

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To determine the feasibility of measuring SpO2 and HR by applying a pulse oximetry probe to the umbilical cord at birth in term neonates undergoing PBCC.

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

Summary

ID

NL-OMON48518

Source
ToetsingOnline

Brief title
PULSE study (Placing UmbiLical Sensor Early at birth study)

Condition

- Other condition
- Neonatal and perinatal conditions
- Neonatal respiratory disorders

Synonym
neonatal changes from intrauterine to extrauterine life, neonatal transition

Health condition

fysiologische neonatale transitie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: neonatal transition, oximetry, umbilical cord

Outcome measures

Primary outcome

The primary outcome will be the proportion of infants who have a reliable

umbilical pulse oximetry signal acquisition within the first 60 seconds after

birth

Secondary outcome

Proportion of infants in whom the umbilical cord oximeter can be successfully

placed

Time from birth to sensor application

Time from sensor application to reliable signal acquisition

Time from birth to reliable signal acquisition

SpO2 (umbilical) at 2 second intervals during the first 10 min after birth

HR (umbilical) at 2 second intervals during the first 10 min after birth

Number of adverse events related to the umbilical cord

Study description

Background summary

Several studies have demonstrated the beneficial effects of delayed cord clamping in infants at birth. This approach is therefore increasingly implemented in clinical practice. Benefits associated with delayed cord

clamping are an increase haemoglobin, hematocrit and a reduction in the risk for iron deficiency anaemia in the first year of life. These beneficial effects have been attributed to the increase in neonatal blood volume from the placenta (placental transfusion).
Heartrate and oxygen saturation are used for clinical evaluation of a newborn, by placing a pulseoximeter sensor on the right hand of the newborn. It is possible reliable signals can be obtained faster when placing the sensor on the umbilical cord. However, it is yet to be determined if pulseoximeter measurements obtained from the umbilical cord are both accurate and obtained faster.

Study objective

To determine the feasibility of measuring SpO2 and HR by applying a pulse oximetry probe to the umbilical cord at birth in term neonates undergoing PBCC.

Study design

Prospective, observational study

Study burden and risks

There are no risks associated with placing or using pulseoximeter sensors. There is a theoretical risk of umbilical arterial vasospasm associated with umbilical cord manipulation when the probe of the oximeter is applied around the umbilicus. Umbilical arterial vasospasm is rarely (3%) observed during invasive procedures9 (umbilical arterial catheterisation). In this study measurements are however non-invasive where the sensor wrap is gently wrapped around the umbilicus, to avoid traction or pressure on the umbilical cord. Hence, the risk associated with umbilical oximeter application is likely to be negligible.
Pulse oximetry is standardly used at birth in infants where clinical evaluation is needed and sensors are specifically designd for (pre)term neonated. We do not expect any other risks concerning the use of this device. The use of the pulse oximeter will not interfere with contact between mother and child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy infants born at Leiden University Medical Centre birth centre.
Gestational age of at least 37 weeks, of multiparous mothers
No need for resuscitation/respiratory support

Exclusion criteria

significant congenital malformations influencing the cardiopulmonary transition
signs of placental abruption or placenta praevia
signs of severe fetal distress necessitating an emergency caesarean section
infants needing respiratory support during transition as the cord will then be clamped immediately
infants born via caesarean section
infants with short umbilical cords, that are unable to be placed at their mothers chest

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):	02-12-2019
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Massimo Radical-7 pulse oximeter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-11-2019
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	NL70932.058.19

Study results

Date completed:	18-06-2020
Actual enrolment:	21