Multisite Near-infrared spectroscopy monitoring in newborn infants at risk of circulatory failure

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON36773

Source
ToetsingOnline

Brief title
NIRS and circulatory failure in newborns

Condition

- Cardiac and vascular disorders congenital
- Bacterial infectious disorders
- Decreased and nonspecific blood pressure disorders and shock

Synonym
circulatory failure, shock

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: circulatory failure, Near-infrared spectroscopy, newborns

Outcome measures

Primary outcome

Primary endpoints:

- Cerebral tissue oxygenation as measured with NIRS:

o Cerebral rSO2 and FTOE

- Mean blood pressure (MABP) as measured with an arterial catheter

Secondary outcome

Secondary endpoints:

- Somatic tissue oxygenation as measured with NIRS:

o Abdominal rSO2 and FTOE

o Renal rSO2 and FTOE

- Clinical hemodynamic factors:

o heart rate

o urinary output

o capillary refill

- Biochemical hemodynamic factors:

o serum lactate

o base excess

- effect of treatment (volume expansion and/or inotropics) on:

o cerebral, abdominal and renal rSO2 and FTOE

o MABP

- Somatic outcome

o Liver function: ASAT/ALAT/LDH/bilirubine

o Kidney function: ureum/creatinine

- Neurologic outcome:

o Will be defined in an extra amendment in the future

Study description

Background summary

Circulatory failure is an important cause of mortality and morbidity in seriously ill newborn infants admitted to the neonatal intensive care unit (NICU). Because clinical and biochemical parameters which are currently used to estimate systemic blood flow are often poor predictors of low systemic blood flow and impaired tissue oxygenation, there is a risk of over- and undertreatment of these infants with the risk of adverse outcome and iatrogenic damage. Near-infrared spectroscopy (NIRS) is a non-invasive method which can be used to measure tissue oxygenation continuously as a bedside monitoring device. By means of NIRS, regional tissue oxygen saturation (rSO2) can be measured which reflects the venous-weighted oxygen saturation of the underlying tissue. Fractional tissue oxygen extraction (FTOE) is thought to reflect the balance between tissue oxygen supply, dependent on tissue perfusion, and tissue oxygen consumption, and can be calculated when rcSO2 and arterial oxygenation (tcSaO2) are measured simultaneously by the following equation: FTOE = (tcSaO2 - rSO2)/tcSaO2. There is some evidence that the combination of somatic and cerebral (multi-site) NIRS monitoring could help to assess systemic blood flow and organ perfusion. If so, multi-site NIRS monitoring could help to diagnose and monitor newborns with impaired organ perfusion at risk of brain injury and organ damage in need of treatment. However, before multi-site NIRS-monitoring can be implemented in clinical care, more information is needed about the value of multi-site NIRS-monitoring as diagnostic tool in newborn infants with circulatory failure. By lack of a golden standard for organ perfusion in neonates, we therefore want to investigate the relation between somatic and cerebral oxygenation on one hand and current hemodynamic parameters and somatic and neurologic outcome on the other hand.

Study objective

The primary goal of this study is to determine if the use of multi-site NIRS-monitoring in newborn infants at risk of circulatory failure could lead to

a better diagnosis, treatment and outcome in these infants compared to the use of conventional used hemodynamic parameters alone. As there is no golden standard for tissue perfusion in newborn infants available, we will relate somatic and cerebral tissue oxygenation to conventional used hemodynamic parameters on one hand and short- and long-term neurologic and somatic outcome on the other hand. Furthermore, we will investigate the effect of currently used interventions on cerebral and somatic tissue oxygenation and hemodynamic parameters

Primary objective:
- to determine the relation between blood pressure and cerebral tissue oxygenation in newborns with circulatory failure due to variable causes

Secondary objectives:
- to determine the relation between blood pressure and somatic (abdominal and kidney) tissue oxygenation in newborns with circulatory failure due to variable causes
- to determine the relation between other hemodynamic parameters (heart rate, capillary refill, urinary output, base excess and serum lactate) and cardiac output as measured with doppler echocardiography on one hand and cerebral and somatic (abdominal and kidney) tissue oxygenation on the other hand in newborns with circulatory failure due to variable causes
- to determine the relation between somatic (abdominal and kidney) and cerebral tissue oxygenation on one hand and somatic and neurologic outcome on the other hand in newborns with circulatory failure due to variable causes
- to determine the effect of various forms of treatment of circulatory failure (e.g. volume expansion, dopamine, dobutamine, hydrocortisone) on somatic (abdominal and kidney) and cerebral tissue oxygenation on one hand and hemodynamic parameters on the other hand in newborns with circulatory failure due to variable causes

Study design

Prospective observational cohort study in which 66 newborn infants at risk of circulatory failure due to patent ductus arteriosus, clinical sepsis or acyanotic congenital heart disease will be included. As soon as the risk of circulatory failure is recognized by the attending neonatologist, newborns will be considered for inclusion. When parental informed consent has been obtained previously, newborns will be included in the study. For cerebral and somatic regional tissue oxygenation monitoring, we will use an INVOS 5100C near-infrared spectrometer (Somanetics Corporation, Troy, MI) and pediatric and neonatal SomaSensors (Somanetics Corporation). The SomaSensors will be placed on three locations: on the left frontoparietal side of the neonate's head (cerebral), 1 cm below the umbilicus (abdominal/splanchnic), and on the left

posterior flank (kidney). We will use an elastic bandage to keep the SomaSensors in place to avoid skin irritation. NIRS-monitoring will be continued for the duration of circulatory failure as decided by the attending neonatologist, but at least for 72 hours. Simultaneous to the NIRS-recordings, pre- and postductal transcutaneous arterial oxygen saturation (tcSaO2) will be measured by pulse-oximetry on the right arm and the leg and FTOE, which is thought to reflect the balance between oxygen supply and oxygen extraction, will be calculated with the following equation: FTOE = (tcSaO2 - rSO2)/tcSaO2.

During the study period, additional clinical and biochemical parameters which give an impression of systemic blood flow, which can influence somatic or cerebral tissue oxygenation or which will give an impression of kidney or liver function will be prospectively gathered during the study period, as part of clinical routine. These data consist of heart rate, blood pressure, urinary output, capillary refill, blood gas values (pO2, pCO2, pH, base excess), serum lactate, glucose concentration, hemoglobin concentration, ASAT, ALAT, LDH, bilirubine, creatinine and ureum. In addition, cardiac output (superior vena cava flow, left ventricular output, right ventricular output) will be assessed once within 48 hours of inclusion by means of doppler echocardiography.

Study burden and risks

The multi-site NIRS measurements are non-invasive and do not interfere with routine clinical care. As cerebral oxygenation monitoring is already part of routine clinical care, only two extra sensors will be applied. Because sensors are held in place by elastic bandages, and are not sticked to the skin, skin irritation is avoided. Hemodynamic parameters will only be collected as part of clinical routine, and do therefore not pose an extra burden on the child. Data from this study can not be obtained in another population, as the intention of this study is to use multi-site NIRS monitoring in neonatal intensive care. In addition, only newborn infants often suffer from circulatory failure as a result of prematurity, patent ductus arteriosus or uncorrected congenital heart disease. The results from this study offer more knowledge about a new monitoring device which could help to identify neonates at risk of brain injury or organ damage earlier and more adequate, and which could help to guide adequate therapy, thereby improving outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

newborns admitted to the NICU of the University Medical Center Groningen at risk of circulatory failure due to patent ductus arteriosus, clinical sepsis or acyanotic congenital heart disease. Risk of circulatory failure will be defined as at least two of the following events: hypotension (<5th percentile for gestational and postnatal age), increased heart rate (>20% above baseline in rest), compromised perfusion (capillary refill > 3 seconds or < 1 second and clinical appearance), oliguria (<0.5 mL/kg/h) and raised lactate or base excess with previously normal pH.

Exclusion criteria

chromosomal abnormalities

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2011
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO

Date:	22-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL34392.042.10