The microcirculation in neonatal adaptation, an observational study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Red blood cell disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39215

Source
ToetsingOnline

Brief title
The microcirculation in neonates

Condition

- Red blood cell disorders
- Vascular disorders NEC

Synonym
Microcirculation, smallest bloodvessels

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Adaptation, Microcirculation, Newborn, Noninvasive Imaging

Outcome measures

Primary outcome

The primary objective in this observational study is to determine microcirculatory profile in preterm and term neonates. We would like to determine how the microcirculation changes in time during the phase of adaptation and correlate inter- and intra-patient variations with clinical signs of maladaptation.

The microcirculation profile consists of:

• Microcirculatory perfusion defined by the parameters PVD and MFI

• RBC deformability defined by Elongation Index

• Cerebral tissue oxygenation defined as cerebral saturation (rScO2), and cerebral fractional tissue oxygen extraction (cFTOE)

• NO metabolism measured by urine nitrite and nitrate concentration

• Formation of ROS measured by urine malondialdehyde

In this study we will examine:

• The relationship between the microcirculation and routinely obtained macrocirculatory parameters

• The relationship between microcirculatory perfusion (defined by the parameters PVD & MFI) and RBC rheology (defined by the parameters RBC deformability)

• The relationship between microcirculatory perfusion (defined by the parameters PVD & MFI) and NO metabolism (defined by the parameters urine nitrite and nitrate)

• The effect of oxygen administration on NO-signaling pathways and ROS formation

• To evaluate if routine treatment options as surfactant administration and red blood cell transfusion improves the microcirculation

Secondary outcome

nvt

Study description

Background summary

The microcirculation is an important, but under-evaluated part in neonatal physiology. Maladaptation in the phase before and after birth has short and long-term consequences. Excessive oxygen administration and thus the formation of reactive oxygen species leads to interferences of the NO pathway and destructive effects on DNA. Neonatal maladaptation is associated with increased risk of cardiovascular disease in adult life.

The ability of the fetus to withstand profound and sustained hypoxia in utero may serve as a model from which to develop strategies to improve survival in hypoxemic critically ill patients. With a better understanding of the relationship between hypoxemia and tissue hypoxia, *permissive hypoxemia* could become a realistic possibility in selected patient cohorts. Simply adding more oxygen at the top of the oxygen cascade may not be the solution to disequilibrium at a tissue level.

Recent technological developments enable us to acquire more detailed information about tissue oxygenation and factors that contribute to the microcirculation. Through the establishment of microcirculatory profiles, knowledge will be acquired for further investigation of predictive value of non invasive functional biomarkers. Ultimately, this may lead to the identification of high risk patients and improved treatment strategies of tissue oxygenation and thereby improved outcome of neonates.

Study objective

The primary objective in this observational study is to determine microcirculatory profile in preterm and term neonates. We would like to determine how the microcirculation changes in time during the phase of adaptation and correlate inter- and intra-patient variations with clinical signs of maladaptation

Study design

Observational study conducted at the Neonatology Intensive Care Unit (NICU) and maternity ward (healthy control group) of the Erasmus MC - Sophia.

Study burden and risks

Due to the observational character of this study, the risks are very small. We aim to assess the objectives mainly using non-invasive techniques. No adverse events have been reported using Cytocam and NIRS. The only possible burden could be that some minor manipulation of the infant may be required to obtain qualitatively good images. Urine samples will be obtained in a non-invasive manner using gauze in the diaper. Blood samples will only be obtained when the infant is already punctured for medical reasons or when an arterial catheter is in place. Because of the low frequency and quantity for determination (3 times 0.1 ml), risk for anemia is small.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Neonates born with a gestational age between 24 weeks and 32 weeks and admission to the(NICU)
- Neonates born with a gestational age after 37 weeks suffering from asphyxia and admitted to the NICU
- Neonates born with a gestational age after 37 weeks and admitted to the maternity ward
- Written informed consent obtained from parent(s) of caregiver(s)
- Age < 24hours

Exclusion criteria

- Age >= 24hours
- Patients with (the suspicion of) hematologic disorders
- Patients with (the suspicion of) lethal congenital malformations
- Absence of written informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	365
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-12-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL40946.078.12