Microcirculatory Shock Occurence in Neonatal Adaptation Research (microSONAR).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21064

Source
NTR

Brief title
microSONAR

Health condition

Adaptation

Sponsors and support

Primary sponsor: Erasmus MC - Sophia
Source(s) of monetary or material Support: Erasmus MC - Sophia

Intervention

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 interand

intra-patient variations with clinical signs of maladaptation. Hereby we like to determine what a normal and what an abnormal microcirculatory profile is.

Secondary outcome

1. The relationship between the microcirculation and routinely obtained macrocirculatory parameters;

2. The relationship between microcirculatory perfusion (defined by the parameters PVD & MFI) and RBC deformability;

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

4. The effect of oxygen administration on NO-signaling pathways and ROS formation;

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

Study description

Background summary

Adaptation after birth is a process which occurs in every newborn. Maladaptation leads to hypoxia and potential toxic oxygen administration. The microcirculation might play an important role in the pathogenesis of maladaptation and may have significant effects on later life. We would like to establish microcirculatory profiles focussed on the first week of life. Hereby we like to determine what a normal and what an abnormal microcirculatory profile is.

Study objective

The microcirculation can be a supportive non-invasive biomarker for making clinical decisions and even help to predict sepsis and mortality in the Neonatal Intensive Care Unit.

Study design

CytoCam and NIRS data will be obtained within the first 24 hours after birth (T1).

Thereafter, measurements will be done on day 3 (T2), 5 (T3) and 7 (T4). If the patient is still admitted to the NICU, measurements will be repeated at day 14 (T5) and day 28 (T6) to complete the neonatal period.

Red blood cell deformability and urine nitrite/nitrate/malondialdehyde will be measured at T1, T2 and T4.

Intervention

This is an observational study. The following techniques will be used to determine microcirculatory profiles:

1. Sidestream Darkfield Imaging and CytoCam;

2. NIRS;

3. Red blood cell deformability using LORCA;

4. Urine samples measuring nitrate/nitrite and malondialdehyde.

Contacts

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Eligibility criteria

Inclusion criteria

1. Neonates born with a gestational age between 24 weeks and 43 weeks;

2. Admission to the NICU or maternity ward;

3. Age <24 hours;

4. Written informed consent obtained from parent(s) of caregiver(s).

Exclusion criteria

1. Age ≥ 24 hours;

2. Patients with the suspicion of hematologic disorders;

3. Patients with the suspicion of lethal congenital malformations;

4. Absence of written informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2013
Application type:	First submission

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
NTR-new	NL3713
NTR-old	NTR3876
Other	METC Erasmus MC : MEC-2012-474
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A