

Microcirculatory Shock Occurrence in Neonatal Adaptation Research (microSONAR).

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21064

Bron

NTR

Verkorte titel

microSONAR

Aandoening

Adaptation

Ondersteuning

Primaire sponsor: Erasmus MC - Sophia

Overige ondersteuning: Erasmus MC - Sophia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus MC - Sophia Children's Hospital

Department of Pediatrics

Room SK-2210

Dr. Molewaterplein 60

Postbus 2060
H.A. Elteren, van
Rotterdam 3000 CB
The Netherlands
+31 (0)10 7036015

Wetenschappelijk

Erasmus MC - Sophia Children's Hospital

Department of Pediatrics

Room SK-2210

Dr. Molewaterplein 60

Postbus 2060
H.A. Elteren, van
Rotterdam 3000 CB
The Netherlands
+31 (0)10 7036015

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age $\geq$ 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	28-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3713
NTR-old	NTR3876
Ander register	METC Erasmus MC : MEC-2012-474
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A