Biomarkers and Asphyxia

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To evaluate the course of concentrations of oxidative stress parameters and neuro-biomarkers in cord blood, serum and urine of full-term asphyxiated neonates. Furthermore, to investigate whether these concentrations are correlated to hypoxic...

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

Summary

ID

NL-OMON35285

Source
ToetsingOnline

Brief title
Biomarkers and asphyxia

Condition

- Encephalopathies
- Neonatal and perinatal conditions

Synonym
hypoxic-ischaemic encephalopathy, oxygen depreviation, perinatal asphyxia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: asphyxia, biomarker, neonates, neurological outcome

Outcome measures

Primary outcome

Measurement of concentrations of oxidative stress parameters (NPBI,

8-isoprostane) and neuro-biomarkers (S100B, NSE and B-FABP) in cord blood,

arterial blood at 0-6, 72, 108 hours and in saliva and urine at 0-6, 8, 12, 16,

20, 24, 36, 48, 72, 96 en 108 hours after birth.

Outcome measurements for hypoxic ischemic brain injury are brain injury on MRI

(day 3-5) or neonatal mortality.

Secondary outcome

Outcome measurements for adverse long-term outcome are neurodevelopmental

abnormalities at 18 months and 5 years of follow-up.

Study description

Background summary

Perinatal asphyxia is a relatively common cause of hypoxic ischemic injury of the full-term neonatal brain in the Netherlands and can lead to perinatal death or cognitive and neuro-motor impairment in later life. Despite the use of clinical encephalopathy scores, amplitude-integrated EEG and MRI for the estimation of severity of brain injury and prognosis, there is still a demand for an early and objective diagnostic and prognostic parameter. Former research suggests that several oxidative stress parameters and neuro-biomarkers could serve as both diagnostic and prognostic tools early after birth in asphyxiated neonates with hypoxic ischemic encephalopathy (HIE). However, more research is necessary to evaluate their diagnostic and prognostic values, which could contribute to better insight into timing of brain injury, improvement of the selection criteria for treatment and to discovery of a valuable tool for treatment evaluation after perinatal asphyxia.

Study objective

To evaluate the course of concentrations of oxidative stress parameters and

neuro-biomarkers in cord blood, serum and urine of full-term asphyxiated neonates. Furthermore, to investigate whether these concentrations are correlated to hypoxic ischemic brain injury and adverse neurological outcome.

Study design

Two-center prospective cohort study.

Study burden and risks

In this observational study there are no therapeutic consequences and patients are subjected to standard clinical care and follow-up. Although participants will not benefit from this study, the goals of this study are clinically relevant for similar patient populations. In addition, risks associated with participation are limited, because samples are obtained non-invasively or with a negligible burden, whearas the amount of withdrawn blood is acceptable for a full-term neonate. Furthermore, outcome measurements are all part of standard clinical care and follow-up in asphyxiated neonates and do not provide an extra burden to participants.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85090
3508 AB Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85090
3508 AB Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Gestational age of at least 37 weeks and two of the following criteria:
- Signs of fetal distress: late decelerations or decreased variability of fetal heart rate on cardiotocography, or meconium stained amnion fluid, or fetal scalp blood ph < 7.2
- Apgar score <=5 at one minute or <= 7 at five minutes
- Arterial cord blood or first pH < 7,00
- Need for ventilation > 5 minutes
- Multi-organ failure

Exclusion criteria

- Congenital malformations
- Documented chromosomal abnormalities
- Inherited errors of metabolism

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2011
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2011
Application type:	First submission
Review commission:	METC NedMec

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	NL29004.041.10