Placental pathology as predictor of neonatal morbidity and neurological outcome in late preterm born infants

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Placental, amniotic and cavity disorders (excl haemorrhages)
Study type	Observational non invasive

Summary

ID

NL-OMON35969

Source
ToetsingOnline

Brief title
Placental pathology and neonatal outcome

Condition

- Placental, amniotic and cavity disorders (excl haemorrhages)

Synonym
placental lesions, placental pathology

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: general movements, late-preterm, placental pathology

Outcome measures

Primary outcome

-Early neonatal morbidity determined by the illness severity during the first

24 hours after birth scored with the SNAPPE-II score.

-Neurological outcome studied by the quality of GMs according to Prechtl*s

method. In addition to the quality of GMs, the motor optimality score will be

obtained for a more detailed analysis of the GMs. GMs will be studied on day

5,8 and 15 after birth, term age and 3 months post term.

Secondary outcome

not applicable

Study description

Background summary

In industrialised countries, preterm birth is responsible for 75 percent of neonatal morbidity and contributes to long-term neurodevelopmental problems. Placental pathology may act as a causative factor in preterm birth. The placenta plays a crucial role during pregnancy, with major implications for the child if its function is impaired. Previous studies in term infants suggested that several placental lesions are associated with long-term neurological morbidity. It is also suggested that several placental lesions are associated with early neonatal morbidity in preterm infants born <32 weeks gestational age (GA). Recently, placental pathology was also reported as being the main cause of foetal death. The most common cause of foetal death in the preterm period is maternal hypoperfusion of the placenta in a pregnancy complicated by hypertensive disorders. In the term period, foetal death is mainly caused by developmental pathology of placenta parenchyma.
Little is known about placental pathology in preterm infants born between 32 and 36 weeks of gestational age, known as the late preterm infants. The question arises whether the association between placental pathology and early

neonatal morbidity and neurological morbidity are the same as seen in early preterm infants (born <32 weeks GA). A method to assess early morbidity is to determine illness severity soon after birth by scoring several clinical variables. A reliable instrument to measure illness severity in the first 24 hours after birth is the Score of Neonatal Acute Physiology Perinatal Extension-II (SNAPPE-II). A non-invasive method to predict neurological outcome in early infancy is the qualitative assessment of general movements according to Prechtl*s method from videotape recordings.

Study objective

The objective of this study is to determine whether placental pathology is associated with early neonatal morbidity and the neurological development in late preterm infants.
We hypothesise that more developmental pathology of the placenta will be found compared to early preterm infants and that placental pathology will be associated with higher illness severity shortly after birth and with a lower quality of GMs.

Primary objectives:
- To determine the association between placental pathology and illness severity during the first 24 hours after birth in infants born between 32 and 35+6 weeks GA.
- To determine the association between placental pathology and neurological outcome during the first 3 months after birth in infants born between 32 and 35+6 weeks GA.

Study design

Prospective observational cohort study in which 70 infants born in the UMCG between 32 and 35+6 weeks gestation will be included. Only singleton infants will be included, because placentas from a multiple pregnancy can show other specific pathologies (e.g. twin-to-twin transfusion). Infants with chromosomal abnormalities will be excluded. The inclusion will take place between 2011 and 2012.
Placentas will be examined by a perinatal pathologist as a part of normal patient care. Illness severity during the first 24 hours after birth will be determined by de SNAPPE-II score. This score consists of 9 clinical variables, which will be retrospectively obtained from medical files. The neurological condition will be evaluated by videotape recordings of the general movements on day 5,8 and 15 after birht, term age and 3 months post term.

Study burden and risks

The qualitative assessment of GMs from videotape recordings is a sensitive non-invasive, non-vulnerable method to assess brain function and to predict

neurological outcome. The non-invasive character of videotaping does not interfere with routine clinical care since the camera will be placed in front of or next to the incubator in a way that caregivers are not hindered by the camera or lose sight on the monitor. Besides, the attending neonatologist and the nurses will be informed that despite the infants being filmed, all necessary care should be continued.
Data from this study can not be obtained in another population, as we are interested in early neonatal morbidity in this specific late preterm infants group. GMs are age-related and are only present from early fetal life onwards until the end of the first half year of life.
The results of this study can help for a better understanding of the mechanisms leading to neonatal morbidity and problems in neurological development in late preterm infants. This insight might bring possible early interventions a step closer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Singleton infants born in the UMCG with a gestational age between 32 and 35+6 weeks.

Exclusion criteria

Chromosomal abnormalities.
Twins and triplets.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2011
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	NL36575.042.11