Late neonatal neurological outcome in infants with prenatally diagnosed duct dependent CHD and its relation with fetal and neonatal cerebral perfusion

Published: 25-04-2014
Last updated: 15-05-2024

First objective: To assess late neonatal neurological outcome in infants with duct dependent CHD and to gain more insight into the timing of brain damage. We will determine whether the quality of GMs at an age of seven days and three months is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40142

Source
ToetsingOnline

Brief title
Perinatal cerebral perfusion in congenital heart disease

Condition

- Congenital cardiac disorders
- Neonatal and perinatal conditions

Synonym
congenital heart defect, heart disease

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: Congenital heart disease, Doppler flow profiles, General movements, Near-infrared spectroscopy

Outcome measures

Primary outcome

Qualitative assessment of GMs according to Prechtl*s method. In addition, we

will obtain motor optimality scores for more detailed analysis of the GMs;

Secondary outcome

Near-infrared Spectroscopy: cerebral (rcSO2) and systemic (rrSO2) oxygen

saturation and FTOE;

Pulsatility index (PI) and if possible maximum velocity of various arterial

vessels, measured with Doppler ultrasound.

Study description

Background summary

Congenital heart disease (CHD) is a common congenital disorder that often leads to neurodevelopmental compromise and potentially a low quality of life. There is increasing evidence that brain damage, which leads to neurodevelopmental compromise, not only occurs during cardiothoracic corrective surgery, but already occurs during early life or even before birth in infants with CHD. In order to prevent brain damage, it is important to know the exact timing of brain damage in CHD. As yet, the exact timing of brain damage in CHD is unknown. To gain more insight in cerebral perfusion in fetuses with prenatally diagnosed CHD, antenatal Doppler flow profiles are routine clinical care at the University Medical Center Groningen (UMCG). Furthermore, postnatally and during cardiothoracic corrective surgery, near-infrared Spectroscopy (NIRS) is a reliable and non-invasive method to assess cerebral and systemic oxygen

saturation, which reflects cerebral and systemic perfusion. However, the combination of antenatal Doppler flow profiles and postnatal and peri-operative continuous cerebral and systemic oxygen saturation measured by NIRS has never been studied in relation to late neonatal outcome in infants with prenatally diagnosed CHD. Late neonatal outcome can be assessed using the qualitative assessment of general movements (GMs) according to Prechtl*s method. The relation between antenatal Doppler flow profiles, postnatal and peri-operative cerebral and systemic oxygen saturation and late neonatal neurological outcome could provide more insight into the timing of brain damage in infants with CHD.

Study objective

First objective: To assess late neonatal neurological outcome in infants with duct dependent CHD and to gain more insight into the timing of brain damage. We will determine whether the quality of GMs at an age of seven days and three months is associated with antenatal Doppler flow profiles in infants with prenatally diagnosed duct dependent CHD. Furthermore, we will determine the relation between the quality of GMs at an age of seven days and three months and postnatal continuous cerebral and systemic oxygen saturation measured by NIRS in infants with prenatally diagnosed congenital heart disease. Secondary objective: To assess whether antenatal Doppler flow profiles are associated with postnatal cerebral and systemic oxygen saturation measured by NIRS. Furthermore, we will analyze the effect of peri-operative NIRS monitoring on GMs by comparing general movements at an age of seven days (pre-operative) to GMs at an age of three months (post-operative).

Study design

Prospective observational cohort study.

Study burden and risks

This study is an observational study, implying minimal extra care; therefore there is almost no burden or risk associated with participation. The study contains three major parameters, i.e. GMs, postnatal and peri-operative continuous multisite NIRS, and antenatal Doppler Flow profiles.
Firstly, GMs is a widely accepted non-invasive method to assess neurological neonatal outcome. At an age of seven days, a camera will be placed in a way that caregivers are not hindered by the camera and do not lose sight on the monitor. Therefore, measurement of GMs at an age of seven days will not interfere with clinical care. At an age of three months the infant will be filmed during an outpatient clinical visit or at home. The infant has to be relaxed and comfortable for a successful GMs analysis. The infant has to have little clothes on (romper) so that every movement is visible. Temperature of the environment will be adapted to this situation.
Secondly, postnatal continuous NIRS is non-invasive and monitoring rcSO2 is

routine clinical care in infants with CHD admitted to the NICU at the UMCG. For the purpose of this study a second sensor will be placed on the left flank of the infant using special bandages (Mepitel®) so that skin irritation is avoided. The sensors will be placed and removed during routine handling moments, so the infant is not disturbed.
Thirdly, antenatal Doppler flow profiles in foetuses with CHD are also non-invasive and routine clinical care at the UMCG.
This study cannot be performed in another study population, because our intention is to assess whether there is an association between GMs and antenatal Doppler flow profiles, and postnatal and peri-operative continuous NIRS monitoring in infants with prenatally diagnosed duct dependent CHD.
This study may provide more insight into the timing of brain damage in CHD, which might be of importance to prevent brain damage and increase quality of life of patients with CHD. We will compare our results with reference values described in literature; no control group will be included.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Mothers of fetusses suspected of CHD and their subsequent newborn infant with duct dependent congenital heart defect
Gestational age > 35 weeks

Exclusion criteria

Large congenital cerebral malformation
Severe chromosomal defect

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2014
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	25-04-2014
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

ID: 23653
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45567.042.14
OMON	NL-OMON23653