The Heart And NeuroDevelopment study - Development of the brain in fetuses and children with severe congenital heart disease

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To establish benchmark values in healthy control fetuses, to compare these with our cohort of fetuses with severe CHD.

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

Summary

ID

NL-OMON40959

Source
ToetsingOnline

Brief title
HAND study

Condition

- Congenital cardiac disorders
- Congenital and peripartum neurological conditions
- Foetal complications

Synonym
congenital-heart-defect structural-heart-disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Congenital-heart-disease, fetalbrain-imaging, neonatal-brain-monitoring, Neurological-development

Outcome measures

Primary outcome

1. brain age of healthy control fetuses (a combined parameter of stages of

development and cortical folding in the brain);

2. brain perfusion of healthy control fetuses;

3. brain volume of healthy control fetuses.

Secondary outcome

1. the development of biometric parameters in healthy control fetuses;

2. the timing of deviation of the aforementioned variables (if they occur, at

what gestational age do abnormalities occur during pregnancy);

3. comparison of early postnatal outcome with prenatal characteristics in

healthy control fetuses.

Study description

Background summary

Congenital heart disease (CHD) is the most prevalent congenital anomaly and accounts for significant (neonatal) mortality and morbidity. Not only cardiovascular and surgical problems can arise, also a high percentage of CHD children suffer from neurodevelopmental disorders. The etiology hereof is considered multifactorial, mainly regarding timing and type of surgery. Recent studies have indicated that some of these neurodevelopmental disorders can

already be present at birth, even before birth. This has prompted the LUMC to change follow up policy of fetuses with CHD, not only monitoring the fetal heart development but also monitoring neurodevelopment. The precise intrauterine and postpartum (perioperative) pathophysiology is however not known. To examine the detailed characteristics of neurodevelopment it is important to compare the findings with healthy control fetuses. This protocol aims to include a control group to the detailed neurosonography (performed in fetuses with CHD).

Study objective

To establish benchmark values in healthy control fetuses, to compare these with our cohort of fetuses with severe CHD.

Study design

This study is a single-center prospective observational cohort study of pregnant women carrying a healthy fetus, and their subsequent children.

In the normal pregnancy, ultrasonography is routinely offered at 20 weeks of GA (structural ultrasound; *SEO*). In our study group, healthy controls will be included for additional detailed ultrasound evaluation of brain development (neurosonography) every 4 weeks,(at GA 20, 24, 28, 32 and 36) and a cranial ultrasound 2-3 days after birth (this is the same follow-up schedule as fetuses with severe CHD undergo routinely).

Study burden and risks

Ultrasound examination in pregnancy and in early neonatal life has been performed for many years and until now no adverse effects have been found.

The fetus and /or the parents can possibly benefit from this study:
- The extra ultrasounds can confirm normal fetal development and reassure the parents;
- The ultrasounds can detect any abnormalities in the growth and/or development of the fetus. For example intra uterine growth retardation is an important risk factor for adverse perinatal outcome and early detection can improve outcome.

The detailed investigation of brain parameters will not directly benefit the fetus and/ or mother.

The results of this study will possibly benefit other fetuses /children and their families by creating local knowledge and know-how

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, women must have a continuing singleton pregnancy of a congenitally normal fetus.

Exclusion criteria

A potential case or control who meets any of the following criteria will be excluded from participation in this study:
- Failure to obtain informed consent
- Maternal age below 18 years;
- Presence of fetal structural anomalies;

- High risk for congenital anomalies.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL48266.058.14