Normal fetal neurodevelopment: healthy control population to compare with fetuses with a congenital heart disease

Published: 27-07-2020
Last updated: 15-05-2024

1.To explore the intrauterine cerebral development by ultrasound in healthy fetuses to compare to the findings in fetuses with severe CHD. We want to do this by establishing benchmark values in healthy control fetuses, to compare these with our...

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

Summary

ID

NL-OMON49553

Source
ToetsingOnline

Brief title
FEND

Condition

- Congenital cardiac disorders
- Congenital and peripartum neurological conditions
- Neonatal and perinatal conditions

Synonym
development-of-the-brain, Neurological-development

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biobank, Congenital-heart-disease, Fetalbrain-imaging, Neurological-development

Outcome measures

Primary outcome

1. Brain age of healthy control fetuses, especially in the third trimester

(cortical folding in the brain)

2. Speed of maturation of healthy control fetuses, especially in the third

trimester

Secondary outcome

1. Brain perfusion of healthy control fetuses

2. Growth trajectories of brain structures,

3. Brain volume of healthy control fetuses

4. Collection of placentas and biomaterial of the umbilical cords for storage

for future research. The biomaterials will be stored in the LUMC Biobank

Verloskunde. The regulations of the LUMC Biobank Verloskunde will be applicable

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. Recent studies have indicated that some of these neurodevelopmental disorders are already present at birth. However, the precise intrauterine pathophysiology is not known. The current study is designed to analyse the normal fetal neurodevelopment and to collect biomaterial of healthy fetuses for the LUMC Biobank Verloskunde, to

serve as a control group for fetuses with congenital heart defects. In the department of fetal medicine of the LUMC, all consecutive CHD fetuses are systematically included in a fetal neurodevelopmental surveillance program (Heart And NeuroDevelopmental Program). Data and biomaterial of fetuses with CHD are stored in the LUMC Biobank Verloskunde.

Study objective

1.To explore the intrauterine cerebral development by ultrasound in healthy fetuses to compare to the findings in fetuses with severe CHD. We want to do this by establishing benchmark values in healthy control fetuses, to compare these with our cohort of fetuses with severe CHD, with regard to 1) brain development, 2) growth trajectories of brain structures, 3) brain perfusion and 4) brain volume.
2. To collect and store placentas and biomaterial of the umbilical cord of healthy control fetuses in our LUMC Biobank congenital heart disease for future research.

Study design

Single-center, prospective, observational cohort study in het LUMC.

Study burden and risks

Prenatal ultrasound provides no risk to the mother and/or fetus as ultrasound is a safe and non-invasive technique.

Burden and risks associated with participation are:
- Risk of unexpected ultrasound findings. However, the chance of encountering a fetal abnormality is very low (<<1%), as all the subjects had a normal second trimester structural anomaly scan before inclusion as part of the national screening program.
- Extra time effort (maximum 5 times 20 minutes)
- In some cases, transvaginal scanning is required, which can be burdensome for some women. Transvaginal ultrasound can be refused by the subjects at any time. As transvaginal scanning is done often in the first trimester for establishing the due date, most women are familiar with the transvaginal ultrasound.

Subjects do not directly benefit from this study. The results of this study will possibly benefit other fetuses/children and their families by creating new knowledge. Insight in normal development of the brain will aid future patients (for example fetuses with CHD or brain abnormalities). By identifying detailed information about timing and mechanism of brain injury in patients with severe CHD, care can be further optimized, neuroprotection programmes can be

developed, and appropriate treatment and support for the individual patients can start as early as possible to improve quality of life and possibly reduce costs of developmental impairments.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Singleton pregnancy
- Normal second trimester ultrasound (absence of abnormalities on ultrasound)
- No use of alcohol, drugs or other psychoactive substances during pregnancy
- Age >= 18 years
- Gestational age 18-36 weeks

Exclusion criteria

- Obstetric history of intra-uterine growth restriction or intra-uterine fetal

demise
- Serious underlying maternal medical condition
- Use of teratogenic medication during pregnancy
- Congenital abnormalities detected in the first year of life

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):	22-10-2020
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	27-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved

Date:	24-04-2024
Application type:	Amendment
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

ID: 26893
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL72889.058.20
OMON	NL-OMON26893