Normal fetal neurodevelopment; healthy control population as a comparison for fetuses with a congenital heart disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26893

Source
Nationaal Trial Register

Brief title
FEND study

Health condition

Congenital heart disease
Intra-uterine neurodevelopmental disorders

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: No funding

Intervention

Outcome measures

Primary outcome

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

Study description

Background summary

Rationale: 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 imaging studies found signs of abnormal neurological development 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.

Objective: To study prenatal normal intrauterine cerebral developmental as a comparison for neurodevelopment in fetuses with CHD, to identify possible prognostic factors for abnormal neurodevelopmental outcome in children
with CHD. 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

Study population: Pregnant women carrying a congenitally normal fetus

Main study parameters/endpoints: brain age, intrauterine development of the brain, speed of maturation

Secondary study parameters/endpoints: brain perfusion, growth trajectories of brain structures, brain volumes, collection of placentas and biomaterial of the umbilical cord for storage in the LUMC Biobank Verloskunde.

Study objective

Fetuses with a congenital heart disease show a delay in cortical maturation especially in the third trimester, in comparison with healthy control cases.

Study design

20-24-28-32 and 36 weeks of gestational age
Birth

Contacts

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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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	04-11-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49553
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9035
CCMO	NL72889.058.20
OMON	NL-OMON49553

Study results