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

Gepubliceerd: 04-11-2020 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26893

Bron
Nationaal Trial Register

Verkorte titel
FEND study

Aandoening

Congenital heart disease
Intra-uterine neurodevelopmental disorders

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

Leiden University Medical Center Albinusdreef 2, 2333 ZA Leiden The Netherlands
Moska Aliasi

+31(0)71 5269199

Wetenschappelijk

Leiden University Medical Center Albinusdreef 2, 2333 ZA Leiden The Netherlands
Moska Aliasi

+31(0)71 5269199

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	04-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49553
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten