

Long-term Effects of selective fetal growth restriction in MONochorionic twins

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The growth-restricted twin will have an increased risk of neurodevelopmental impairment, cardiovascular disease, impaired lung function and suboptimal growth later in life as opposed to its appropriately-grown co-twin.

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

Samenvatting

ID

NL-OMON24670

Bron

NTR

Verkorte titel

LEMON

Aandoening

Selective fetal growth restriction (sFGR), monochorionic twins.

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: The Dutch Heart Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The project addresses five primary objectives:

- I. To assess long-term neurodevelopmental outcome using cognitive tests
- II. To assess long-term cardiovascular outcome using cardiac ultrasound
- III. To assess long-term pulmonary outcome using spirometry
- IV. To assess long-term growth by evaluating childhood growth patterns
- V. To assess long-term (epi)genetic changes by evaluating DNA methylation patterns in buccal swabs

These outcomes will be examined in a large cohort of MC twins with sFGR and compared between the small and the large twin.

Toelichting onderzoek

Achtergrond van het onderzoek

Selective fetal growth restriction (sFGR) in monochorionic (MC) twin pregnancies is characterized by a large intertwin growth discrepancy due to unequal placental sharing. Neonatal morbidity and mortality associated with sFGR have been thoroughly described, but data on long-term outcomes is lacking although we know that fetal growth restriction (FGR) in singletons has been associated with an increased risk of neurodevelopmental impairment (NDI), cardiovascular disease (CVD), impaired lung function and suboptimal growth later in life. Knowledge of long-term outcomes is essential both for adequate counselling of parents of these vulnerable patients and for early identification of children who will benefit from additional postnatal monitoring. Moreover, a better understanding of long-term outcome might aid in devising feasible management options in the future. Therefore, insight into long-term outcomes is crucial in providing the highest standard of care for MC twins with sFGR. The results of this study will be complementary to the Twinlife study (NL67331.058.18) which is already ongoing at the LUMC.

The main objective is to assess long-term neurodevelopmental, cardiovascular, pulmonary, and growth outcomes in a cohort of MC twins with sFGR and to compare outcomes within sFGR twin pairs. The study population consists of all MC twin pairs with sFGR born in the LUMC between 2002 and 2017. We defined sFGR as a birth weight discordance (BWD) $\geq$ 20%.

To assess long-term neurodevelopmental outcome, cognitive and motor development will be evaluated using standardized psychometric age-appropriate tests and a neurological examination. Echocardiography will be used to assess differences in structural cardiac measures and cardiac function, including aortic pulse-wave velocity (aPWV) and carotid intima-media thickness (cIMT). Spirometry will be recorded in children $\geq$ 4 years old to quantify lung function, including forced vital capacity (FVC), forced expiratory volume in one second (FEV1) and forced mid-expiratory flow rate (FEF(25%-75%)). Growth will be assessed using available childhood growth curves from the primary care system and by detailed anthropometric measurements.

Doel van het onderzoek

The growth-restricted twin will have an increased risk of neurodevelopmental impairment, cardiovascular disease, impaired lung function and suboptimal growth later in life as opposed to its appropriately-grown co-twin.

Onderzoeksopzet

Parents and children are asked to fill in part of questionnaires at home prior to the follow-up examinations. Two examinations will be scheduled, one for the neurodevelopmental assessment, growth measurements and the buccal swab and one for the echocardiography and spirometry.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

To be eligible to participate in this study, a subject must meet all the following criteria:

- MC twins with sFGR born in the LUMC.
- Children aged 2 to 17 years at time of inclusion.
- Children currently living in the Netherlands.

The parents of a potential subject must meet the following criteria:

- Parent(s) aged ≥ 18 years, who are able to consent.

- Written informed consent from both parents to participate, form being approved by the Ethic Committee.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- MC twins with TTTS or TAPS.
- Twin Reversed Arterial Perfusion (TRAP).
- Monoamniotic twin pregnancies.
- Children passed away before inclusion.
- Single survivors.
- Children born with congenital/chromosomal abnormalities.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	05-01-2021
Aantal proefpersonen:	132
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 27-10-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9833
Ander register	METC-LDD : P20.089

Resultaten