Neonatal outcome after cardiovascular remodelling in fetal growth restriction

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To explore cardiovascular remodelling with subsequent altered cardiac function (assessed as strain rate) in extremely premature neonates (born

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON51270

Source
ToetsingOnline

Brief title
NeoLifeS - Heart II

Condition

- Neonatal and perinatal conditions

Synonym
delayed growth, fetal growth restriction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac function, cardiovascular remodelling, fetal growth restriction

Outcome measures

Primary outcome

Altered cardiac function subsequent to cardiovascular remodelling in preterm born FGR neonates compared to non-FGR preterm neonates, assessed as the left ventricular longitudinal strain rate using STE. An altered cardiac function will be defined as a left ventricular longitudinal strain rate that is significantly different from the reference values of -1.6 - -1.9/s in the term neonatal population, and -1.5 - -1.7/s in preterm neonates.

Secondary outcome

1) The association between early cardiac function and short-term morbidity

a. The development of PH.

b. The presence of impaired CAR and short-term cerebral injury (ultrasound and general movements (GMs)).

c. The development of NEC, as a potential complication partly due to reduced abdominal tissue oxygenation.

2) The relation between postnatal left ventricular longitudinal strain rate with regular foetal cardiac assessment, and associated factors with the postnatal delta strain rate

3) Maternal and neonatal risk factors including FGR for suboptimal cardiac function, and associations with PH, impaired CAR, short-term morbidity; neurodevelopmental outcome; mortality.

Study description

Background summary

NeoLifeS is an ongoing prospective observational cohort study in which data of preterm born neonates admitted to the University Medical Center Groningen (UMCG) are being collected from standard medical care. This study aims to improve the quality of care for preterm born neonates.
NeoLifeS-Heart was a substudy in preterm born infants, that focused on the cardiovascular problems affecting a substantial part of this patient population, including early and late pulmonary hypertension. We now propose a second substudy within NeoLifeS to assess cardiovascular complications in very preterm born infants after fetal growth restriction (FGR), or small for gestational age (SGA).
Preterm born neonates have an immature vascularization of various organs and are therefore at risk of damage to several organ systems, such as the lungs with bronchopulmonary dysplasia (BPD) and pulmonary hypertension (PH), the intestines with necrotizing enterocolitis (NEC), and the brain with impaired cerebrovascular autoregulation (CAR) and subsequent cerebral haemorrhage or ischemia. Neonates born after FGR encounter even worse complications, in part due to compensatory mechanisms, such as brain-sparing and increased cardiac output resulting in cardiovascular remodelling. The worldwide incidence of FGR is 7-10%. Depending on the definition and the birth weight, BPD prevalence ranges between 23-57%, and the prevalence of PH lies between 8-18%. Additionally, FGR neonates display impaired CAR more often than non-FGR neonates. All these complications together negatively affect the quality of life and survival of preterm born and FGR neonates. Knowledge regarding risk factors, the incidence, prevalence, and occurrence of compensatory mechanisms is lacking but necessary to improve patient care. This NeoLifeS-Heart II study aims to explore these aspects of prematurity and FGR to guide optimized patient care, improving the outcome and prognosis of this patient population.

Study objective

To explore cardiovascular remodelling with subsequent altered cardiac function (assessed as strain rate) in extremely premature neonates (born <30 weeks and/or birth weight < 1000 gram) with FGR.

Study design

Prospective case-control study

Study burden and risks

The data collected within NeoLifeS are part of standard medical care. In addition to this, echocardiograms will be recorded within the first week after birth (preferably up to and including day 4), and once for follow-up after approximately 6 months during a visit to the outpatient clinic. During

admission to the neonatal intensive care unit (NICU), echocardiography is performed at least once in approximately 25% of the patients for clinical reasons. A part of these patients will receive follow-up echocardiography upon their visit to the outpatient clinic. The echocardiograms for this study will be combined with those performed for standard clinical procedures for the neonatal echocardiographies. Any additional echocardiograms will only be performed if this is clinically safe for the participant according to the treating physician. The echocardiography will take approximately 30 minutes of the patient*s time in total. A potential benefit for the participants is the early detection and therefore earlier treatment of cardiac abnormalities.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Admission to the NICU of the UMCG

Gestational age <30 weeks and/or birth weight <1000 gram
Informed consent of the guardian/parent(s).

Exclusion criteria

Declined participation
Major chromosomal abnormalities/congenital abnormalities (such as abdominal wall defects)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-04-2023
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL82734.042.22