Speckle Tracking Echocardiography as a Tool for Early Diagnosis of Impaired Fetal Growth Twin Pregnancies

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This proposal aims to evaluate the use of STE as a diagnostic tool for early diagnosis of impaired fetal growth in twins. The results from this proposal will be beneficial from a public health perspective, as it will lead to accurate and early…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Foetal complications
Study type	Observational invasive

Summary

ID

NL-OMON56687

Source
ToetsingOnline

Brief title
HEART

Condition

- Foetal complications

Synonym
fetal growth restriction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair ziekenhuis Gent, België
Source(s) of monetary or material Support: Eigen middelen dienst Vrouwenklinie;UZ Gent

Intervention

Keyword: speckle tracking echocardiography, twin pregnancy

Outcome measures

Primary outcome

* to evaluate speckle tracking echocardiography in twin pregnancy

* to create reference values of strain and strain rate during twin pregnancy.

Secondary outcome

* to evaluate speckle tracking echocardiography as a tool for early diagnosis

of impaired fetal growth in twin gestations

* to investigate the intra-pair differences in fetal growth and cardiac

remodeling in twin pregnancy

* to compare cardiac remodeling between singletons and twin pregnancies

* to investigate the association between placenta functioning and in utero

cardiac remodeling.

* to explore in utero cardiac remodeling in association with neonatal

cardiovascular health

* to explore the association between maternal and/or fetal complications

and deviating deformation paramters.

Study description

Background summary

Fetal growth restriction (FGR) occurs in 5-10% of the pregnancies and up to two times more in twins than singletons. Early detection during pregnancy is of vital importance to provide optimal care. Still, less than 25% of the FGR cases are currently detected before birth, and hence, optimal care cannot be given.

As a result, FGR is the second leading cause of perinatal morbidity and mortality. It has been associated with a four-fold higher risk of fetal and neonatal complications and a lifelong increased risk for health problems, especially in twins. Diagnosis of FGR during pregnancy is currently based on fetal biometry in combination with Doppler ultrasound. Nevertheless, accurate detection remains difficult due to the small size of the fetal heart and the fetal position and movement. Furthermore, the current techniques do not allow antenatal differentiation between constitutionally small fetuses, who do not require ante- or postnatal care adjustments, and fetuses who are growth restricted due to a pathological cause and who do require intensive care.

Study objective

This proposal aims to evaluate the use of STE as a diagnostic tool for early diagnosis of impaired fetal growth in twins. The results from this proposal will be beneficial from a public health perspective, as it will lead to accurate and early diagnosis of FGR with subsequent antenatal and postnatal care adjustments, and hence, decreased morbidity and mortality. First we have to explore if speckle tracking echocardiography can be used in twin pregnancies and if so, we have to set up reference values of normal growth during twin pregnancy.

Study design

In this prospective study there are 2 time points during the pregnancy included, namely at 21 weeks and 30 weeks of gestation, to measure the predictive values of FGR, strain and strain rate. The fetal growth parameters will be collected at the same time points, to define the growth (differences) throughout gestation of both fetuses.

Study burden and risks

The burden and risk associated with the participation is extremly low.
At 21 weeks gestation, a blood sample is taken for the study. The patient can have a bruise due to the procedure of blood sampling.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

dichorionic twin pregnancy
gestational age of 21 weeks at the first study visit
Women >= 18 years

Exclusion criteria

Women pregnant of multiples of higher order (>=3 siblings)
Monochorionic twin pregnancy
Fetal arrhythmia
Known fetal congenital or genetic abnormalities
Any suspicion of congenital fetal anomalies that might influence fetal cardiac function
Pre-existing maternal hypertensive disease
Autoimmune disease including systemic lupus erythematosus
History of stillbirth
Diabetes mellitus (mother)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-06-2024
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
ClinicalTrials.gov	NCT05423665
CCMO	NL85315.015.23