Validation of echocardiographic features in foetuses

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To establish normal reference values for the foetal LVIRT and myocardial contraction duration using respectively echocardiographic Doppler tracings and cTDI at a foetal age around 20, 28 and 30 weeks* gestation. These reference values will be...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON55695

Source
ToetsingOnline

Brief title
Foetal echocardiographic features

Condition

- Cardiac arrhythmias

Synonym
long QT syndrome, LQTS

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: vakgroep kindercardiologie/AMC

Intervention

Keyword: foetal echocardiogram, left ventricular isovolumetric relaxation time, long-QT-syndrome, myocardial contraction duration

Outcome measures

Primary outcome

The LVIRT and the myocardial contraction duration will be measured using

respectively echocardiographic Doppler tracings and cTDI at a foetal age around

20, 28 and 30 weeks* gestation.

Secondary outcome

Other mechanical foetal echocardiographic parameters at 20, 28 en 30 weeks'

gestation.

Study description

Background summary

The congenital long-QT syndrome (LQTS) is an inheritable cardiac arrhythmia disorder and is associated with sudden cardiac death (SCD) due to malignant ventricular arrhythmias. When LQTS presents in utero or during the first week of life, the prognosis may be poor. Timely appropriate therapy can manage foetal arrhythmias and reverse foetal heart failure and thus early diagnosis may be lifesaving even in the perinatal period. The foetal echocardiogram is the main diagnostic tool for evaluating foetal arrhythmias providing accurate information about the atrial and ventricular contractions that indirectly reflect the P-wave and QRS-complex. Currently echocardiography cannot assess a derivative of the QT-interval. In order to improve the role of the foetal echocardiogram in the diagnosis of LQTS, mechanical parameters that theoretically would be the correlation of the cardiac repolarization have been studied. Mechanical abnormalities in the contraction and relaxation pattern in adult and paediatric LQTS-patients were found and could be used for the diagnosis and risk-stratification in LQTS. These abnormalities can be detected with echocardiographic Doppler tracings and colour Tissue Doppler Imaging (cTDI). Follow up studies found that LVIRT and the myocardial contraction duration were prolonged in LQTS-foetuses and had a high distinctive character for the diagnosis of LQTS and a strong correlation with the QT-interval.

However, establishment of normal ranges of the LVIRT and myocardial contraction duration in healthy foetuses is needed. Furthermore, these previous results should be validated in a larger cohort of LQTS foetuses.

Study objective

To establish normal reference values for the foetal LVIRT and myocardial contraction duration using respectively echocardiographic Doppler tracings and cTDI at a foetal age around 20, 28 and 30 weeks* gestation. These reference values will be compared with foetuses with postnatally confirmed LQTS.

Study design

This is a prospective observational cohort study.

Study burden and risks

In this echocardiogram Doppler tracings and cTDI recordings will be obtained around week 20, 28 and 30 weeks* gestation. In order to do this, patients will be asked to come to the Academic Medical Center in Amsterdam for three additional times. This study does not have an advantage for the participating patients. However, these additional examinations will be performed by a paediatric cardiologist who will first confirm that the foetus has a normal heart. This knowledge could be of emotional benefit to the mother. Should an abnormality be detected the normal management of that problem will be initiated. Women who are pregnant with a foetus with a 50% risk of LQTS will be asked to come to the hospital for two extra visits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

* The mother must be living in The Netherlands.
* The mother is between 18 and 40 years of age.
* The mother should be pregnant and have had standard obstetric care without abnormalities

Exclusion criteria

* Maternal medical history of conditions that are at risk for affecting the foetus (i.e pregestational diabetes, epilepsy, HIV, hepatitis B)
* Maternal use of medication that affects the QTc-interval (https://crediblemeds.org/pdftemp/pdf/CombinedList.pdf)
* Foetuses of consanguineous parents
* Foetuses with congenital heart disease, chromosomal syndromes, cephalic disorders
* Maternal cigarette or alcohol usage during pregnancy
* Maternal obesity before pregnancy (BMI * 30)
* Abnormalities on the previous foetal ultrasound.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-12-2019
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	28-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL69502.018.19