Hemodynamic adaptation of the right ventricle in monochorionic twin pregnancies complicated by twin-to-twin transfusion syndrome or selective growth restriction

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The primary objective of this study will be to evaluate the cardiac adaptation due to hemodynamic changes in monochorionic twin pregnancies complicated by TTTS and sIUGR, by evaluating the size and the growth pattern of the pulmonary artery and the...

| Ethical review | Approved WMO |
|-----------------------|------------------------------|
| Status | Recruitment stopped |
| Health condition type | Congenital cardiac disorders |
| Study type | Observational non invasive |

Summary

ID

NL-OMON41328

Source ToetsingOnline

Brief title HEARTTS

Condition

- Congenital cardiac disorders
- Foetal complications
- Neonatal respiratory disorders

Synonym heart failure, pulmonary stenosis

Research involving

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Human

Sponsors and support

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

Intervention

Keyword: Arteria Pulmonalis, Monochorionic, RVOTO (Right Ventricular Outflow Tract Obstruction), sIUGR (selective intrauterine growth restriction), TTTS (twin to twin transfusion syndrome)

Outcome measures

Primary outcome

The size and growthpattern of the pulmonary artery at the level of the valve,

expressed in standard deviations from the mean (according to Shapiro et al.28).

Secondary outcome

1. The growth curve of the pulmonary artery, the maximum velocity (Vmax) curve

of the pulmonary artery and veins in

- TTTS or sIUGR with development of RVOTO .
- TTTS or sIUGR without development of RVOTO.
- Twins of uncomplicated MCDA pregnancies
- 2. The MPI and Tissue Doppler of the myocard of the right ventricle in fetusses

in complicated monochorionic twin pregnancies, compared with fetusses in

uncomplicated monochorionic twin pregnancies.

Study description

Background summary

Congenital heart disease occurs more frequently in neonates who survived Twin

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to Twin Tranfusion syndrome (TTTS) and selective intrauterine grwoth restriction (sIUGR) than in neonates after uncomplicated pregnancies. Around 7 % of the recipients in monochorionic twin pregnancies complicated by TTTS will develop right ventricle outflow tract obstruction (RVOTO). The incidence in donors of TTTS or the biggest twin in sIUGR is still unknown. The pathogenesis of RVOTO is not yet fully understood.

Neonatologists must be aware of this cardiovascular abnormality, because RVOTO may be progressive and require immediate treatment or surgery after birth. Understanding the pathogenesis and developmental patterns of RVOTO can aid an early detection of RVOTO and could improve prenatal and neonatal care of this complicated pregnancies in the future.

Study objective

The primary objective of this study will be to evaluate the cardiac adaptation due to hemodynamic changes in monochorionic twin pregnancies complicated by TTTS and sIUGR, by evaluating the size and the growth pattern of the pulmonary artery and the right ventricle function in the recipient twin. In this way we can evaluate etiology and pathogenesis of RVOTO, as well as determine risk factors for and/or prognostic factors in RVOTO.

Study design

Observational prospective cohort study.

Women pregnant with monochorionic twin pregnancies, both complicated as uncomplicated, receive ultrasound examinations at least biweekly. In subjects included in this study additional measurements focused on pulmonary artery size and growth, right ventricle function and flow velocity waveforms of pulmonary artery and veins of the recipient twin will be added to the measurements according to local protocol. In complicated cases the frequency of the examinations can be higher on clinical indication and depends on the specific situation of the patient. Additional measurements will be done maximum once a week.

Study burden and risks

No risks are known for prenatal ultrasonographic examination. A minimal burden is prolonged ultrasonographic examination time. Next to the routine (at least biweekly) ultrasound in these high-risk pregnancies which normally takes about half an hour, some extra measurements will be done in about 5-10 minutes.

The potential benefit for participating is an early and accurate diagnosis of RVOTO for the foetusses of the participating woman, leading to adequate post

partum care by neonatologists as well as adequate counseling pre-partum.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

* All women pregnant of monochorionic twins

* Ability to give informed consent

Exclusion criteria

- * Fetuses with non-cardiac congenital anomalies
- * Fetuses with chromosomal abnormalities

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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: | Recruitment stopped |
| Start date (anticipated): | 01-04-2015 |
| Enrollment: | 220 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|-------------------------------------|
| Date: | 02-03-2015 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |
| Approved WMO | |
| Date: | 04-07-2017 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

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 |
|----------|----------------|
| ССМО | NL45251.058.13 |

Study results

| Date completed: | 30-11-2018 |
|-------------------|------------|
| Results posted: | 26-09-2019 |
| Actual enrolment: | 188 |

First publication

01-01-1900