Urinary markers and fetal growth restriction

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22664

Source
Nationaal Trial Register

Brief title
-

Health condition

Fetal growth restriction (FGR) occurs in 10% of all pregnancies. FGR is multifactorial, as it is associated with various conditions, like maternal diseases, chromosomal abnormalities and infections. Placental insufficiency, resulting in hypoxia, is the most important underlying mechanism in FGR. In most of the cases the fetus doesn¡¦t reach its biological growth potential due to placental insufficiency. These fetuses with FGR are born preterm and have an increased risk for short and long-term morbidity and mortality. They have a higher risk on neurological developmental disorders and a higher risk of cardiovascular diseases on the long term.

Keywords: fetal growth restriction, FGR, metabolite, diagnostic, hydrogen sulfide, sulfate, urine, markers

Keywords dutch: foetale groeirestrictie

Sponsors and support

Primary sponsor: Stimuleringsfonds verloskunde (kleine vis-grote vis)
Source(s) of monetary or material Support: Self-financing research??

Intervention

Outcome measures

Primary outcome

Urinary and blood metabolites of the transsulfuration pathway (thiosulfate, sulfite,sulfate).

Secondary outcome

o Doppler patterns in umbilical artery and median cerebral artery (MCA)

o composite neonatal outcome

o composite maternal outcome

o placental findings

o placental bed findings

o methylation differences

o immunologic differences

Study description

Background summary

There is need for early predictors for FGR that are easy to measure, inexpensive and, preferably, easy to sample. It is known that several gaseous signaling molecules such as H2S, CO and NO play a role in the (compensatory) mechanism of FGR since they are involved in blood pressure regulation, inflammation and reactive oxygen (ROS) scavenging.
In this pilot study we aim to find a predictive marker with possible therapeutic potential for FGR that is easily available, non-invasive and inexpensive.

Study objective

Currently, a major issue in fetuses with FGR is the diagnostic process. Children born below a certain population based centile are either constitutionally small or growth restricted. Children grown above that centile may be growth restricted although their weight seems to be normal. If we use p10 as a cut off we know that 50% of babies indicated as FGR are in fact healthy small babies and we miss 50% of babies who are growth restricted and are grown above the p10. The distinction between FGR and small for gestational age (SGA) fetuses is

important, because where FGR fetuses are pathologically small (irrespective of the growth percentile), SGA fetuses are physiologically small. Consequently, these SGA fetuses are at low risk for adverse perinatal outcomes.

The objective of the study is to find a (non-invasive) biomarker in the urine of pregnant women, which can predict, in combination with biometrical and Doppler measurements, the (severity of) occurence of fetal growth restriction (FGR. Biomarkers we are interested are metabolites of hydrogen sulfide (transsulfuration pathway) that are excreted in the urine (e.g. sulfate which is the most stabile metabolite).

Our hypothesis is that gaseous vasoactive molecules influence placental vasomotor activity to compensate for hypoxemia. Metabolites of these vasoactive molecules can be found in the urine and blood and can indicate whether this (compensatory) mechanism is used to enhance placental function.

Study design

Primary outcomes:

Concentrations of metabolites of the transsulfuration pathway in the urine, measured by ELISA procedures.

Secondary outcomes:

placental histology, metabolites in maternal and fetal blood, APGAR-score, Doppler abnormalities.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

Group 1:

o Pregnant women aged 18-40 years

o Between 24 - 36 weeks of pregnancy

o Diagnosed with FGR:

„X AC/EFW
„X Pulsatility index (PI) umbilical artery >p95 or PI uterine artery >p95

o No other comorbidities

o Group 1A: FGR diagnosed before 34 weeks of gestation (early late)

o Group 1b: FGR diagnosed after 34 weeks of gestation (late early)

Group 2:

o Pregnant women aged 18-40 years

o Diagnosed with FGR (early or late):

„X AC/EFW
„X Pulsatility index (PI) umbilical artery >p95 or PI uterine artery >p95

o Diagnosed with hypertension according to the WHO criteria (sBP > 140mmHg and dBP > 90 mmHg)

Group 3:

o Pregnant women aged 18-40 years

o Between 24 - 36 weeks of pregnancy

o Diagnosed with SGA

„X EFW
o No comorbidities

Group 4:

o Pregnant women aged 18-40 years

o Between 24 - 36 weeks of pregnancy

o Estimated growth between 40th and 60th percentile

o No comorbidities

Exclusion criteria

o Congenital anomalies

o Being unable to understand the study information either caused by language differences or low IQ

o Ruptured membranes

o Diabetes Mellitus (defined as use of insulin)

o Renal disease

o Seropositive for HIV

o HELLP

o Urinary tract infection at the moment of collecting urine.

o Multiple pregnancies

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2016
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 32015
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6048
NTR-old	NTR6187
CCMO	NL20160.018.07
OMON	NL-OMON32015

Study results