First trimester differences in ultrasound parameters between pregnancies complicated by uteroplacental insufficiency and uncomplicated pregnancies: an observational study

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Primary objective: To investigate whether there are differences in Doppler ultrasound (US) parameters measured during the routine 13-week scan between pregnancies complicated by uteroplacental insufficiency (UPI) and pregnancies not complicated by…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Placental, amniotic and cavity disorders (excl haemorrhages)
Study type	Observational non invasive

Summary

ID

NL-OMON49914

Source
ToetsingOnline

Brief title
FIT-study

Condition

- Placental, amniotic and cavity disorders (excl haemorrhages)

Synonym
malfunctioning placenta, Uteroplacental insufficiency

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pregnancy, Ultrasound, Uteroplacental insufficiency

Outcome measures

Primary outcome

Difference in Doppler US parameters measured during the 13-week scan in the

uteroplacental insufficiency (UPI) population and the non-UPI population.

Secondary outcome

Biomarker analyzes in 13-week blood samples between pregnancies complicated by

UPI and non-UPI.

Study description

Background summary

Important pregnancy complications, such as preeclampsia (PE) and fetal growth restriction (FGR) share uteroplacental insufficiency (UPI) as a common pathophysiology. PE and FGR represent a major concern in public health, affecting 2-8% and 5-10% of all pregnancies, respectively, and are a leading cause of perinatal morbidity and mortality. For UPI and its subsequent pregnancy conditions, no causal treatment is available, besides adequate fetal monitoring and timely delivery.
Estimating the risk for UPI and its high-impact pregnancy complications is challenging in daily practice. Literature demonstrates that predictive accuracy for FGR (as a consequence of UPI) is minimal to low for FGR-related biomarkers; at least when independently deployed.(3) It is unknown whether possible biomarkers related to placental dysfunction are altered in the first trimester already; before clinical features of UPI are manifest (e.g. hypertension and proteinuria for PE). At the time of clinical presentation, UPI is reflected in the resistance to blood flow in the uterine arteries (maternal) and umbilical (placental) arteries, which can be measured by Doppler US. It is unknown whether these changes are already present in the first trimester, especially in fetuses with late-onset FGR (>=32 weeks of pregnancy (as a consequence of UPI). Especially the accuracy of the diagnosis of FGR with a late onset is poor.

We aim to investigate whether there are differences in Doppler US parameters and possible biomarkers measured during the 13-week scan between pregnancies complicated by UPI and pregnancies not complicated by UPI. Prospectively evaluating this in the first trimester of pregnancy might be a stepping stone towards a 1st trimester screening strategy for UPI based on Doppler US and possible biomarkers could have additional value in this. Such a newly to develop screening algorithm would allow clinicians to make a risk assessment, early in pregnancy with the possibility of intervening by means of antiplatelet agents or intensified fetal monitoring; this might prevent or milden the consequences of UPI. With the 13-week scan now being part of standard prenatal care in the Netherlands, clarifying the additional value of such a strategy could be extremely valuable.

Study objective

Primary objective:
To investigate whether there are differences in Doppler ultrasound (US) parameters measured during the routine 13-week scan between pregnancies complicated by uteroplacental insufficiency (UPI) and pregnancies not complicated by UPI.
Secondary objective:
To study differences in other possible biomarkers, such as serum samples in pregnancies complicated by UPI compared to pregnancies not complicated by UPI, sampled during the routine 13-week scan.

Study design

Observational prospective study.

Study burden and risks

The study population consists of singleton pregnant women undergoing a 13-week scan in the UMCG in the context of a combined test (cT) and/or indicated screening anomaly scan. The ultrasound (US) exam and including measurements at 13 weeks gestational age are in the context of a routine cT and/or an indicated screening anomaly scan. In the context of the study we ask permission of the participant for including these data in the research database, analyzing the recorded data and withdrawal of 2 extra bloodsamples (taken during the visit for the scan).

To evaluate whether uteroplacental insufficiency (UPI) develops during pregnancy, fetal growth and Doppler profiles should be measured later on in pregnancy. The US exam and including measurements at 20 weeks gestation is in the context of standard prenatal care in the Netherlands. In the context of the study we ask permission of the participant for including these data in the research database and analyzing the recorded data.

In the context of the study we ask the participant to return for an additional US of circa 15 minutes at >=32 weeks gestation, where we will again evaluate fetal growth and Doppler profiles (thus UPI). Blood withdrawal is only necessary during the 13-week scan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Singleton pregnant women referred for a routine 13-week scan to the UMCG in the context of a cT and/or indicated screening anomaly scan will be included.

Exclusion criteria

Age <18 years;
Chromosomal abnormalities;
Fetal demise during pregnancy, not caused by uteroplacental insufficiency;

Termination of pregnancy;
Congenital anomalies;
Suspected/proven infections;
Pregnant women not capable of a reasonable valuation of its interests in the matter.

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:	Will not start
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO Date:	18-10-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-03-2022
Application type:	Amendment
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	NL78556.042.21

Study results

Summary results
Trial never started