Placenta perfusion and sufficiency study

Published: 02-05-2023
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To assess the feasability of measuring placental perfusion by measuring the placental and uterine blood vessels and maternal haemodynamic function in women with singleton pregnancies between 14- and 16-weeks*gestational age.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Placental, amniotic and cavity disorders (excl haemorrhages)
Study type	Observational non invasive

Summary

ID

NL-OMON53343

Source
ToetsingOnline

Brief title
P2S-study

Condition

- Placental, amniotic and cavity disorders (excl haemorrhages)
- Vascular hypertensive disorders

Synonym
placenta dysfunction, placenta insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Geen financiering

Intervention

Keyword: Insufficiency, Perfusion, Placenta, Ultrasound

Outcome measures

Primary outcome

The assessment of the reproducibility of measuring the placental perfusion in

women with singleton pregnancies between 14- and 16-weeks*gestational age

Secondary outcome

1. To assess whether it is possible to repeatedly measure the blood

velocity and diameter of the uterine arteries and veins, and umbilical arteries

and vein.

2. What are the differences in measurements between the two umbilical arteries?

3. Does a relation between the uterine artery and vein flow exist?

4. Does a relation between the umbilical arteries and vein flow exist?

5. The assessment of intra-observer variability.

Study description

Background summary

The placenta is the connection between foetal and maternal blood flow. The placenta is thus an essential organ that delivers the nutrition needed for the growth of the foetus. The uterus, the organ that houses the placenta, undergoes changes from the moment of conception and throughout pregnancy to accommodate the needs of the placenta and the foetus. There are many maternal and foetal pathologies that are related to the mismatch between blood flow needs of the foetus and the ability to provide the adequate blood flow from the uterus and placenta. This leads us to our current search for an accurate and reproducible way to measure placental perfusion.

Study objective

To assess the feasability of measuring placental perfusion by measuring the placental and uterine blood vessels and maternal haemodynamic function in women with singleton pregnancies between 14- and 16-weeks*gestational age.

Study design

pilot study, prospective cohort.

Study burden and risks

Patients are burdened by having an extra visit to the outpatient clinic. During this visit, the participants would spend approximately 1 hour in a horizontal position to be able to complete all measurements. Added benefits associated with this study is the possibility to have an extra moment to see the baby by ultrasound.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18 years or higher
- Between 14-16 weeks gestation
- Placenta anterior
- BMI <30 kg/m2
- Ability to give consent
- Adequate mastery of Dutch or English language

Exclusion criteria

- Non-intact pregnancy
- Vanishing twin
- Multiple gestations
- Congenital or anatomical anomalies

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):	11-08-2023
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	02-05-2023

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
CCMO	NL83681.015.23