Development of a new 3D virtual desktop imaging technique for real time non-invasive evaluation of the utero-placental interface vascularization throughout pregnancy.

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Part I Preclinical study using the VIRTUAL preclinical prototype Primary objective:- To validate the reliability and applicability of regular use of the VIRTUAL (pre)clinical prototype in a bed-side setting (desktop) preconceptional and across...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON44711

Source
ToetsingOnline

Brief title
VIRTUAL

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Placental development

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3D Virtual Desktop Imaging, Pregnancy, Real time, Utero-placental interface vascularization

Outcome measures

Primary outcome

Part I Preclinical study using the VIRTUAL preclinical prototype

Intra- and inter-observer agreement of the measurement of the indices of

placental vascularization.

The indices measured are the following:

- Preconception uterine vascular bed:

Volume of endometrial vasculature (VEV)

Total volume of vasculature (TVV)

Uterine artery (left and right) pulsatility and resistance

- Placental vascularization:

Placental Bed vasculature Volume (PVBV)

Fetal vascular volume (FVV)

Total volume of vasculature (TVV)

Uterine artery (left and right) pulsatility and resistance

Part II Clinical study using the VIRTUAL clinical prototype

Indices of the preconception uterine vascular bed (PREC) and indices of

placental vascularization (PREG) measured by the VIRTUAL clinical prototype.

The indices measured are the following:

- Preconception uterine vascular bed:

Volume of endometrial vasculature (VEV)

Total volume of vasculature (TVV)

Uterine artery (left and right) pulsatility and resistance

- Placental vascularization:

Placental Bed vasculature Volume (PVBV)

Foetal vascular volume (FVV)

Total volume of vasculature (TVV)

Uterine artery (left and right) pulsatility and resistance

Secondary outcome

The relationship between the indices of the preconception uterine vascular bed (PREC) together with the indices of placental vascularization (PREG):

a) Maternal biomarkers (blood)

b) (Pre)clinical outcomes (embryonic and fetal (head) growth trajectories,miscarriage, preeclampsia, gestational age at delivery, and birth weight)

c) Maternal conditions and lifestyle (medication use, intoxications, infections, physical activity, working activities, body mass index (BMI), blood pressure, nutrition, smoking, alcohol and folic acid supplement use)

Study description

Background summary

Early placental development plays a critical role in human reproduction. Development of the placental vascular bed is not only related to adverse pregnancy outcomes, but has also been shown to be associated with maternal and child health during the life course. Impaired placental development is thought to contribute to the occurrence of non-communicable diseases. Several periconception maternal environmental influences, in particular lifestyle like nutrition and smoking, interact with placental development and functioning, but are also related to preconceptional (sub)endometrial and uterine vascularization.

Hence, knowledge on placental development needs to be expanded in the second and third trimester of pregnancy, but also during the first trimester of pregnancy. Therefore, there is a need for a patient-friendly, rapid, non-invasive and safe evaluation technology that can be applied throughout pregnancy, cross-linking clinical information, including maternal environmental influences, and placental development and functioning with novel morphological and quantitative data on the placental bed vasculature.

The rationale for the evaluation of maternal lifestyle in relation to fetal development is based on epidemiological and animal studies. However, maternal lifestyle also has an impact on placental vascularization and development, but it is not known how lifestyle operates or whether lifestyle affects the vasculature of the nonpregnant uterus. Therefore, we will study associations between maternal lifestyle and uterine and placental indices obtained by the non-invasive technology (i.e. VIRTUAL clinical prototype). If in future patients with poor lifestyle can be identified, lifestyle, modification of these behaviours could create a healthy placental environment thereby optimizing health for mother and unborn child.

Study objective

Part I Preclinical study using the VIRTUAL preclinical prototype
Primary objective:
- To validate the reliability and applicability of regular use of the VIRTUAL (pre)clinical prototype in a bed-side setting (desktop) preconceptional and across pregnancy. During the first trimester preferably, only placental structures will be scanned using power Doppler and as such the embryo lies outside the Doppler ultrasound beam.

Part II Clinical study using the VIRTUAL clinical prototype
Primary objective:
- To investigate the development of the uterine- and utero-placental

circulation and intra-placental vascularization of the preconception nonpregnant uterus and the placenta across pregnancy.

Study design

Part I Preclinical study using the VIRTUAL preclinical prototype:
A pilot observational cohort study will be performed in (non)-pregnant women to investigate 3D power Doppler scans obtained of the preconception uterine vascular bed and placenta during pregnancy using the VIRTUAL preclinical prototype.

Part II Clinical study using the VIRTUAL clinical prototype:
An observational cohort study will be performed in nonpregnant (PREC cohort) and pregnant women (PREG cohort). To investigate 3D scans using the VIRTUAL clinical prototype.

Study burden and risks

For all participants the risks involve primarily the burden of participating in a study, which usually means additional hospital visits and assessments. The risks of participation are considered to be minor and the potential benefit outweighs the risks. From the above, it is clear that there are no obvious risks associated with participation in the study.

The availability of a safe, near real-time, non-invasive, rapid, easy-to-use and cheap method of relating maternal conditions and lifestyle and clinical outcomes to uterine and placental bed vascularization, will have a high impact on current clinical practice. The development of VIRTUAL may lead to the use of maternal biomarkers to assess uterine and placental function, the amelioration of clinic decision-making based on imaging alone versus imaging in combination with assessment of biomarkers and might provide future intervention strategies eventually leading to life-long reduced risk of non-communicable diseases. Therefore, this project will have an impact on research, clinical care individual and public health as well as on future medical health care costs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Women * 18 and 45 * years of age, planning a pregnancy or < 10 weeks pregnant.
2) Understanding of Dutch (Erasmus MC) in speaking and reading.
3) Willingness to be in the study for 1 month (PREC) and/or around 7 months (PREG) for the assessments using the VIRTUAL clinical prototype.
4) Willingness to give written informed consent.

Exclusion criteria

1) Women unable or unwilling to give informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2016
Enrollment:	520
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL54342.078.15