The Ome-study, a pilot: the logistics and characterization of a placental, neonatal and (fe)male periconceptional microbiome, virome and metabolome

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To establish a functional working protocol to analyze, characterize and determine the microbiome (including the virome) and its metabolome of the placenta, neonate and periconceptional semen and vaginal/cervical/uterine/rectal environment.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON53006

Source
ToetsingOnline

Brief title
The Ome-study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
periconceptional period, period around the beginning of pregnancy

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,ZonMW

Intervention

Keyword: and metabolome., and microbiome., Periconceptional male and female microbiome, Placental and neonatal microbiome, virome

Outcome measures

Primary outcome

To establish a functional work protocol for analyzing, characterization and

determination of the periconceptional, placental and neonatal microbiome and

metabolome.

Secondary outcome

Not applicable.

Study description

Background summary

Placental-related pregnancy complications (preeclampsia, preterm birth, fetal growth restriction) originate in the first weeks of pregnancy and are due to suboptimal implantation and placentation. In order to improve the perinatal and maternal outcome of placental-related complications, we need to understand the combined periconceptional microbiome and its metabolome. By linking different microbiome compositions and its metabolome to different pregnancy outcomes, we want to develop novel biomarkers to predict optimal implantation and placentation.

Study objective

To establish a functional working protocol to analyze, characterize and determine the microbiome (including the virome) and its metabolome of the placenta, neonate and periconceptional semen and vaginal/cervical/uterine/rectal environment.

Study design

Part 1a+b: An observational cohort study as pilot in periconceptional women and

men and women after elective caesarean section (aged 18 - 45 years) and neonates delivered by an elective caesarean section.

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. Secondly, all participating men will be asked to produce a semen specimen by masturbation. All women have to participate in a physical examination (a speculum exam to obtain vagina/cervical and/or uterine swabs)) and a rectum swab (this could be collected by the self-collection if preferred by the patient). Women participating have to deliver in the Erasmus MC in order to collect the placental microbiome. Extra information can be obtained from residual material, questionnaires, and extra material (blood, urine, saliva from the participants). 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 establishment of a safe and rapid work protocol to determine the placental, neonatal and periconceptional microbiome and metabolome could be used in the future to predict pregnancy outcome and will have a high impact on current clinical practice. The assessment and determination of an optimal periconceptional microbiome in combination with the metabolome may lead to the use of new biomarkers to assess placental function 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)
Newborns

Inclusion criteria

1) Part 1a: Men and women >= 18 and 45 <= years of age, healthy and in the periconceptional period or couples contemplating pregnancy and visiting the preconception and reproductive life planning clinics at the Erasmus MC.
2) Part 1b: Women >= 18 and 45 <= years of age who will undergo an elective term caesarean section.
3) Understanding of Dutch in speaking and reading.
4) Part 1a: Willingness to undergo a speculum examination (female) or produce a semen specimen (male).
5) Written informed consent.

Exclusion criteria

1) Men and women unable or unwilling to agree with the physical examination and procedures.
2) Men and women unable or unwilling to give written informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	31-08-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-02-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-04-2022
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	NL61077.078.17