Composition of vaginal microbiota in preeclamptic patients, an explorative study

Published: 24-11-2016
Last updated: 14-04-2024

To determine the vaginal microbiota composition during preeclampsia

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43092

Source
ToetsingOnline

Brief title
Preeclampsia and microbiota

Condition

- Autoimmune disorders
- Maternal complications of pregnancy
- Vascular disorders NEC

Synonym
preeclampsia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: microbiota, preeclampsia

Outcome measures

Primary outcome

Primary outcome of the study is to determine the composition and subsequently

the difference of the vaginal microbiome between the patients with preeclampsia

and the uncomplicated pregnancies.

Secondary outcome

not applicable

Study description

Background summary

Human microbiota composition has a critical role in health and host response modulation, therefore microbiota composition is most likely crucially important for mother and fetus during pregnancy. It was reported that the vaginal microbiota composition is less diverse during pregnancy, majorly dominated by two species of Lactobacillus, in order to maintain the acidic pH and to inhibit growth of opportunistic pathogens in the vagina. However little is known about the composition of vaginal microbiota during pregnancy disorders such as preeclampsia. The pathogenesis of preeclampsia involves aberrant inflammation and inadequate innate and cellular immune activation suggesting a possible implication of the microbiome as well. Dysbiosis of the vaginal microbiome can be associated with pregnancy complications and can influence the conventional neonatal gut microbiota.

Study objective

To determine the vaginal microbiota composition during preeclampsia

Study design

Observational explorative tudy

Study burden and risks

Vaginal swabs will be taken during regular pregnancy routine check-up, which will not affect the regular number of visits to the hospital/midwife clinic, nor will pose an extra risk for the individuals. This study investigates preeclampsia associated vaginal microbiota changes which might be different from the regular pregnancies and therefore may lead to possible therapeutic treatments. None of the subjects will have a direct benefit of this study.

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

-signed informed consent

-age: 18- 40 years
-healthy
- first pregnancy
- between 25-35 weeks pregnant
- preeclampsia (defined as blood pressure >=140/90 on more than two occasions 4 hours apart, plus proteinuria on a random urine sample)

Exclusion criteria

-vaginal bleeding
-vaginal infection
-urinary tract infection
-use of antibiotics
-body mass index <18 and >30

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:	Recruiting
Start date (anticipated):	24-10-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2016
Application type:	First submission
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	NL58341.042.16