Changes in gut- and vaginal microbiome composition in association with PCOS clinical phenotypes

Published: 11-10-2022
Last updated: 06-04-2024

The main objectives of this study is to analyze differences in the gut and vaginal microbiome between healthy and PCOS women and investigate whether these differences correlate with PCOS characteristics. In addition, we want to look at a possible...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON51568

Source
ToetsingOnline

Brief title
GuVa PCOS study

Condition

- Endocrine disorders of gonadal function

Synonym
polycystic ovary syndrome

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: gut microbiome, PCOS, vaginal microbiome

Outcome measures

Primary outcome

Differences in community structure of the gut microbiome between PCOS patients and controls as such and its diagnostic and metabolic characteristics.

Secondary outcome

- Differences in community structure in the vaginal microbiome between PCOS patients and controls as such and its diagnostic and metabolic characteristics.

- Differences and similarities in community structure of the vaginal- and gut microbiome in PCOS patients

- Differences and similarities between the vaginal- and gut microbiome composition between overweight/obese and lean patients (with/without PCOS)

- To analyse potential metabolic profiles characterizing different phenotypes of PCOS

Study description

Background summary

Polycystic ovary syndrome (PCOS) is an endocrine disorder that affects up to 10% of the reproductive-aged women worldwide. The etiology is still unknown and treatment therefore remains symptomatic. Studies indicate a possible role of the gut microbiome in the pathology of PCOS. PCOS women have a disturbed gut microbiome, with certain species associated with the PCOS characteristics: hyperandrogenism, ovarian dysfunction, obesity, glucose intolerance and insulin resistance. Although differences have been found in gut microbiome composition between PCOS and healthy women, the literature is inconclusive regarding the

difference in gut microbiome biodiversity. Studies examining the vaginal microbiome in PCOS women show consistent results with specific species in the vaginal microbiome. However, there are only few studies on the vaginal microbiome in PCOS women and no studies have yet investigated the correlation between sex-specific hormones and PCOS characteristics. More research is needed to understand the function of the microbiome in the pathophysiologyof PCOS, so that this can offer perspectives in future therapies.

Study objective

The main objectives of this study is to analyze differences in the gut and vaginal microbiome between healthy and PCOS women and investigate whether these differences correlate with PCOS characteristics. In addition, we want to look at a possible correlation between the vaginal and gut microbiome in PCOS patients. Finally, we will look at differences in microbiome composition between obese and non-obese PCOS women.

Study design

Case control study

Study burden and risks

Patients diagnosed with PCOS using the COLA screening (abbreviation for Cycle Disorder, Oligomenorrhoea and Amenorrhoea) and who agree to participate in the GuVA study, will receive the PIF at the appointment of the COLA screening result. The COLA screening is part of the regular care at the Reproductive Medicine outpatient clinic, which means that in addition to completing a questionnaire and physical examination, a gynecological ultrasound is also performed. These data will be used for the GuVa study in agreement with the patient. When the patient agrees to participate, she will receive instructions to collect a portion of feces and bring it on the day of the second appointment.
On the second appointment, a vaginal swab is taken (without speculum) by the researcher. On the same day, additional blood parameters will be obtained for the GuVa study. Finally, patients are asked to complete a food frequency questionnaire online.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40 40

Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age 18-45years (premenopausal)
- Caucasian
- Willing to provide vaginal swab and stool sample
- Willing to provide informed consent
- Sufficient command of the Dutch language
- Diagnosed with PCOS at Erasmus MC using the Rotterdam criteria by a presence of at least two of the following criteria
o Clinical or biochemical hyperandrogenism (modified Ferriman-Gallway score >5; testosterone level >2nmol/L, Free Androgen Index > 2.9)
o Oligomenorrorrhea or amenorrhea
o Polycystic ovaries.

Control group:
o Age 18-45years
o Caucasian
o Willing to provide vaginal and stool sample
o Willing to provide informed consent
o Regular menstrual cycle (25-35days)
o Sufficient command of the Dutch language

o No history of diagnosed PCOS and do not meet any of the Rotterdam criteria.

Exclusion criteria

- BMI <18
- Smoking
- Diabetes Mellitus or use of insulin sensitizer
- Chronic and acute infection diseases
- Endometriosis (American Fertility Score (AFS) III/IV)
- Elevated prolactin levels, thyroid disease, Cushing disease or gastro-intestinal disease
- The use of hormonal contraceptives, other steroid hormones in last 3 months
- Use of antibiotics, probiotics or laxatives in the last 3 months

The exclusion criteria also applies to the control group

Study design

Design

Study type:	Observational 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):	17-10-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	11-10-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-04-2023
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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL80648.078.22