

# Analysis of expression differences between endometria of women with PCOS and normal cycling women, collection of normal endometrial tissue

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1. Evaluation of gene-expression profiles of endometria of PCOS women compared to normal ovulatory women  
2. Identify genes and pathways which contribute to a high rate of miscarriages of PCOS women  
3. Identify genes and pathways related to the high...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Ovarian and fallopian tube disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON39161

### Source

ToetsingOnline

### Brief title

Genexpression profiles of endometria of PCOS women

### Condition

- Ovarian and fallopian tube disorders

### Synonym

polycystic ovary syndrom

### 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:** endometrium, Gene-expression profile, polycystic ovary syndrom (PCOS)

## Outcome measures

### Primary outcome

- Determine endometrial gene-expression profiles from women with a normal regular cycle and from PCOS women
- Determine basal levels for E2, LH, FSH, AMH, prolactin, free testosterone, SHBG, DHEA-S, and 17-hydroxyprogesterone (17-OHP) of control patients and PCOS patients
- Identify endometrial genes and pathways contributing to PCOS related infertility.

### Secondary outcome

Not applicable

## Study description

### Background summary

PCOS (Polycystic Ovary Syndrome) is a common endocrine and metabolic disorder in women in the reproductive age. It is the most common cause of anovulatory infertility, and its prevalence is estimated to be 5-10%.

The currently accepted definition of PCOS involves the combination of at least two of the following features: chronic anovulation, clinical or endocrinological signs of hyperandrogenism and polycystic ovaries (PCO) assessed by ultrasound.

Women with PCOS have a lower fecundity rate. Infertility associated with PCOS derives from chronic anovulation, but there are increasing data suggesting that poor oöcyt quality, implantation failure, and higher rates of miscarriage further complicate achieving and maintaining a pregnancy in women with PCOS. Miscarriage rates have been reported to be between 30 and 50%, and 30% of women

with recurrent miscarriages are reported to have PCOS. Moreover, PCOS women have a significantly higher risk of endometrial hyperplasia and endometrial cancer. If these women develop endometrial cancer it is at an earlier age as compared to non PCOS women (mean age 40 compared to 64 years of age). The endometrium is the inner layer of the uterus, and undergoes a rapid cycling process of proliferation, differentiation and cell death due to the production of the ovarian hormones, estrogen and progesterone. In women with PCOS who are anovulatory, the regulatory roles of progesterone and progesterone withdrawal in the endometrium is absent or suboptimal. As a result, the tissue is continuously exposed to estrogens, and does not undergo the sequential changes in gene expression and associated biochemical processes resulting in normal endometrial cellular proliferation, differentiation, and tissue desquamation. There is increasing evidence of dysregulated expression of biomarkers in the epithelium of the endometrium of women with PCOS, for example  $\alpha\beta3$  integrin, ER $\alpha$  and a dysregulation in the IGF (insulin-like growth factor) system.

The aim of this study is to understand dysregulated signalling pathways in the endometrium of PCOS women by analyzing expression profiles using a pathway-oriented method.

## **Study objective**

1. Evaluation of gene-expression profiles of endometria of PCOS women compared to normal ovulatory women
2. Identify genes and pathways which contribute to a high rate of miscarriages of PCOS women
3. Identify genes and pathways related to the high incidence of endometrial cancer in PCOS women

## **Study design**

The study is an analysis of endometrial gene-expression profiles of PCOS patients and normal ovulatory control women.

## **Study burden and risks**

Risk and burden are linked to protocol procedures, such as blood withdrawal, ultrasound and biopsy sampling. Although these are routine procedures, carried out by medical qualified personnel, they may cause side effects or discomfort to the subject. However, it is expected that these procedures will generally be well tolerated.

The patient is asked to come once to the hospital and a questionnaire is sent to her. At the study visit the blood and endometrium samples are collected, and the ultrasound is performed.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Regular menstrual cycle (between 25 and 35 days)
- BMI >18 and <27
- Age 18 and above
- normal serum FSH levels (1-10 IE/l)
- normal serum prolactin levels (<1 U/l)
- normal TSH levels (0.2-4.2 mU/l)
- normal internal genitals as observed by ultrasound

### Exclusion criteria

Women which are diagnosed with endometriosis (based on clinical findings, questionair,

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gynaecological examination, transvaginal ultrasound or laparoscopy).

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	10
Type:	Actual

## Ethics review

Approved WMO	
Date:	15-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	18-11-2013
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**

<b>Register</b>	<b>ID</b>
CCMO	NL28923.078.09