Sexual function in women with Polycystic Ovary Syndrome

Published: 23-06-2016
Last updated: 19-07-2024

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

Summary

ID

NL-OMON54548

Source
ToetsingOnline

Brief title
PCOS and sexual function

Condition

- Endocrine disorders of gonadal function
- Sexual dysfunctions, disturbances and gender identity disorders

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: PCOS, polycystic ovary syndrome, sexual dysfunction, sexual function

Outcome measures

Primary outcome

1. General sexual function as measured with the FSFI, SDI, FSDS-R

2. Genital sexual responsiveness (VPA) and self-reported ratings of subjective sexual responsiveness and affect (7 point Likert scale) from the psychophysiological measurements.

Secondary outcome

1. The association between OCP use and general sexual function and genital sexual responsiveness.

2. The association between sexual parameters as measured with SESII-W, SPAQ and SES and genereal sexual function and genital sexual responsiveness.

3. Psychosocial parameters as measured with MBSRQ-AS, BISS, HADS, RSES and R-DAS

4. Steroid hormone levels (Testosterone, Sex Hormone Binding Globluline (SHBG) calculating Free Androgen Index: Testosterone x 100/SHBG), Oestradiol, Progesterone, Luteinizing-hormone (LH), FollicleStimulating-hormone (FSH), Androstedione, Dehydro-epiandrosterone (DHEA), Dehydro-epiandrosterone sulphate (DHEAS), Thyroid Stimulating Hormone (TSH), Prolactine, and fasting glucose and insulin)

5. Androgen receptor sensitivity as measured with CAG repeats

Study description

Background summary

Polycystic Ovary Syndrome (PCOS) is the most common endocrine disease in women in the reproductive age and is often accompanied with changes in androgen levels. It is associated with physical and psychological co-morbidities. Treatment often consists of prescribing oral contraceptives (OCP), which influence androgen levels. Androgen levels as well as other physical and psychological factors influence sexual function. Studies concerning sexual function in women with PCOS show conflicting results and often do not address all contributing factors.

Study objective

to assess general sexual functioning, genital sexual responsiveness, subjective sexual responsiveness and affect in women with PCOS , and to make a comparison of these results with the results of an age matched healthy control group of women.

Additionally, to assess associations between OCP use, biopsychosocial variables, endocrine features (sex steroid concentration), CAG repeat length, BMI , biographical features and scores on psychosocial questionnaires (SESII-W, SPAQ, SES, MBSRQ-AS, BISS, HADS, RSES, R-DAS) and general sexual functioning and genital and subjective sexual responsiveness in women with PCOS and an age matched healthy control group of women.

Study design

Case control study, observational prospective, multi-center.
Duration of the study: 3 years
Setting of the study: Academic Medical Clinics (Erasmus MC, LUMC, AMC)

Primary study aim
The difference between PCOS patients and healthy control women will be assessed by sexological questionnaires (FSFI, SDI, FSDS-R) and psychophysiological measurements (VPA) and self-reported subjective sexual responsiveness.

Participants will be subjected to an experimental session measuring genital sexual responsiveness with photoplethysmography (VPA) and subjective sexual responsiveness under 4 conditions of sexual stimuli. The stimuli that will be used are 1) a fantasy only stimulus, 2) a vibratory only stimulus, 3) a vibratory and film stimulus and 4) a film only stimulus.

Secondary study aims
Additionally for the secondary study aims PCOS patients and healthy control women will be assessed by other sexological questionnaires (SESII-W, SPAQ, SES) and other psychosocial and mental health questionnaires (MBSRQ-AS, BISS,

HADS, RSES, R-DAS). Scores on these questionnaires, endocrine features (sex steroid levels), CAG repeat length, BMI, biographical and biopsychosocial factors will be correlated with scores on FSFI, SDI, FSDS-R AND and VPA.

OCP users will be compared to non-OCP users on FSFI, SDI, FSDS-R and VPA scores in both the PCOS patients and control women.

Independent variables are PCOS status and OCP use.
Dependent variables are general sexual function (measured with FSFI, FSDS-R, SDI,SESII-W, SPAQ, SES) and genital and subjective sexual responsiveness (measured with VPA).

The study will be performed in three phases.
First, we will compare general sexual function (FSFI, SDI, FSDS-R) and genital (VPA) and subjective sexual responsiveness between PCOS women and healthy control women irrespective of OCP use.
Second, we will compare scores on FSFI, SDI, FSDS-R and VPA between women using OCP*s and women not using OCP*s, both PCOS patients and control women.
Third, we will compare general sexual function (FSFI, SDI, FSDS-R) and genital (VPA) and subjective sexual responsiveness in PCOS women in a longitudinal design assessing them first not using OCP*s and assessing them second after using OCP*s for three months.

After a year, all participants will be asked to give consent to repeat the endocrine screening in order to determine changes in the PCOS phenotype in the same subject over time and to determine the reliability of the screening over time.

This study is a multi-center study. The principal investigator (Pastoor) is trained as a psychologist and sexologist. The Department of Obstetrics and Gynaecology has proven research expertise in diagnosing, treating and predicting treatment outcome in women with fertility problems especially in those suffering from PCOS. Current research focuses, among others, on life-style modification and on pathophysiological mechanisms of PCOS and their genetic background.
Cooperation with LUMC (Both, Weijenborg) and AMC (Laan) is sought because of their excellent and extended expertise in sexological research, both using questionnaires and vaginal photoplethysmography.

Study burden and risks

There will be no benefits for the individual participants. However, the results of the study will provide PCOS patients with more knowledge about their condition, which might improve quality of life. The results of this study also will be of clinical use for the education and treatment of women with PCOS.
Disadvantages might be the time invested in the participation in the study, having to undergo one peripheral venous blood sample, having to fill in

questionnaires of an intimate nature, and having to undergo vaginal measurements .
The vaginal photoplethysmograph used in this study is considered a save device. No harmful events have been reported. The device will be sterilized before each use. From previous studies at the LUMC and AMC it is known that the genital measurement does not cause discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

diagnosis of PCOS and age-matched controls (healthy women)
age: 18-40 years
stable heterosexual relationship for at least 6 months

Exclusion criteria

a psychiatric disorder, pregnancy or lactation, having undergone a radical hysterectomy or prolaps surgery, current or recent use of medication or medical disorders (other than PCOS) that may influence sexual response.

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):	19-02-2017
Enrollment:	356
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	20-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-07-2024
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	NL55484.078.16
Other	NL7583