Sexual function in women with Polycystic Ovary Syndrome

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24133

Source
NTR

Brief title
PCOSseks

Health condition

Polycystic Ovary Syndrome

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam
Source(s) of monetary or material Support: Erasmus MC, Department of Obstetrics & Gynecology, Reproductive Medicine

Intervention

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 general 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

Rationale: 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.
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
Study population: PCOS patients, 18-40 years old. Control population of age matched healthy women. All women have to be in a stable heterosexual relationship for at least 6 months. In both groups we aim at including as many women using OCP’s as not using OCP’s.
Main study parameters/endpoints:
General sexual functioning: Female Sexual Function Index (FSFI), Sexual Desire Inventory (SDI), Female Sexual Distress Scale-Revised (FSDS-R).
Genital sexual arousal: vaginal pulse amplitude (VPA) measured with photoplethysmography during an experimental session with different erotic stimuli: a self-induced erotic fantasy, a vibration only stimulus, erotic film only and vibratory stimulation combined with erotic film.
Subjective sexual arousal and affect: self-reported ratings of sexual arousal and positive and

negative affect collected after each stimulus condition.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

Hypotheses following from the literature:
Primary hypotheses:
- we expect to find impaired results in PCOS patients compared with normal controls on the following subjective measures of sexual function: FSFI, SDI, FSDS-R
- we expect to find higher responses in PCOS patients than in normal controls on genital and subjective sexual responsiveness measured with VPA in both the fantasy only and vibratory only conditions

Secondary hypotheses:
- We expect PCOS women not using OCP's (i.e. with hyperandrogenism) to show higher levels of VPA response in the fantasy only and vibratory only conditions than PCOS women on OCPs and normal controls with or without OCP. Control women using OCP's are expected to show the lowest VPA levels in these two conditions .
- We expect to find no differences in VPA response between PCOS patients and normal controls during film conditions.
- We expect women with PCOS to show impaired results and higher distress levels as measured with SESII-W, SPAQ, SES, MBSRQ-AS,BISS, HADS, RSES, R-DAS compared with control women.
o We expect these scores to be associated with impaired scores on FSFI, SDI and FSDS-R, but not with VPA scores.
- We do not expect to find an association between endocrine features and scores on FSFI, SDI and FSDS-R in both the PCOS patients and control women.
- We expect to find a stronger positive correlation between endocrine features (sex steroid concentrations) and VPA scores in the fantasy only and vibration only condition in PCOS women but not in control women.
- We expect to find better sexual function (FSFI, SDI, FSDS-R, VPA) in women with either longer or shorter CAG repeat length in both the PCOS patients and the control women.

Study design

NA

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

diagnosis of PCOS and age-matched controls (healthy women without PCOS).

Both women with PCOS and healthy women will be selected in a group not using hormonal contraceptives (for at least 3 months prior to the start of their participation in this research project) and a group using hormonal contraceptives for at least 3 months.

We aim to include as many women using OCP’s as not using OCP’s in both the PCOS group and the control group.

All participants need to be aged between 18 years – 40 years and be in a stable heterosexual relationship for at least 6 months.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

In case of a psychiatric disorder, pregnancy or lactation, having undergone a radical hysterectomy or prolapse surgery, current or recent use of medication or medical disorders (other than PCOS) that are known to influence sexual response, with the exception of OCP’s.

In general:

No selection will be made based on the presence or absence of the wish to get pregnant or parity.

In case women do not want to participate in the psychophysiological part of the study, they will be excluded.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2017
Enrollment:	144
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-03-2019
Application type:	First submission

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
NTR-new	NL7583
CCMO	NL-55484.078.16, METC2016-216

Study results