

# Effect of concomitant treatment with an androgen on sexual functioning in women using an oral contraception

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| <b>Submission date</b><br>19/11/2009   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>21/12/2009 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>14/10/2019       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
PR3042

## Study information

**Scientific Title**

A double-blind, placebo controlled, randomised, comparative 2-way crossover study to determine the effect of concomitant treatment with an androgen on sexual arousability and the vascular component of the sexual arousal response during self-induced erotic fantasy and visual stimulation in women using oral contraception

**Acronym**

ARC-AMC study

**Study objectives**

To determine the effect of concomitant dehydroepiandrosterone (DHEA) compared to placebo in the two treatment groups of oral contraception (OC) users on different aspects of sexual functioning.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Medische Etische Commissie (AMC) approved on the 18th March 2007 and 13th September 2007

**Study design**

Double-blind placebo controlled randomised comparative 2-way crossover study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Hormonal anticonception

**Interventions**

Each cycle (28 days), daily intake of:

1. Microgynon® (150 µg levonorgestrel [LNG]/30 µg ethinyl estradiol [EE]) or Yasmin® (3 mg drospirenone [DRSP]/30 µg EE); on day 1 - 21
2. 50 mg DHEA or placebo in two tablets; on day 1 - 28

Pretest period: 1 cycle (no OC)  
Treatment period 1: 5 cycles  
Treatment period 2: 5 cycles  
Total treatment duration: 10 cycles (each cycle: 28 days)

## **Intervention Type**

Drug

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Dehydroepiandrosterone, Microgynon® (levonorgestrel [LNG], ethinyl estradiol [EE]), Yasmin® (drospirenone [DRSP], EE)

## **Primary outcome measure**

1. Sexual arousability, sexual desire, and frequencies of sexual fantasies as assessed with the sexual function diary completed during the last two treatment cycle of each treatment period; each treatment period consists of 5 treatment cycles (each cycle: 28 days)
2. Sexual function as assessed with the Female Sexual Function Index (FSFI) and Female Sexual Distress Scale-Revised (FSDS-R), at screening, pretest, study visit at end of each treatment period
3. Vaginal pulse amplitude (VPA) during sexual stimulation and experience of sexual arousal during sexual stimulation, at pretest visit, study visit at end of each treatment period

## **Secondary outcome measures**

1. Androgen parameters, measured at screening, pretest visit, study visit at end of each treatment period
2. Daily hassles, completed during the last two treatment cycles of each treatment period
3. Health diary, completed during the last two treatment cycles of each treatment period
4. Haemostasis metabolism, measured at screening, pretest visit, study visit at end of each treatment period
5. Bleeding data, measured with diary keeping during both treatment periods
6. Safety assessment, measured throughout the study

## **Overall study start date**

01/05/2007

## **Completion date**

01/07/2009

# **Eligibility**

## **Key inclusion criteria**

1. Healthy females between 20 and 35 years of age
2. Using OC for at least three consecutive cycles prior to screening
3. Stable, heterosexual relationship for at least 3 months prior to screening
4. Willing to interrupt OC use for a period of 4 weeks
5. Regular menstrual cycle (24 - 35 days) prior to last start of OC use
6. Body mass index (BMI) between (greater than or equal to) 18 and (less than or equal to) 35 kg

/m<sup>2</sup>

7. Good physical and mental health

8. Sign a written informed consent agreement

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

84

**Total final enrolment**

81

**Key exclusion criteria**

1. Maudsley Marital Questionnaire (MMQ) General Marital Satisfaction Scale Score greater than or equal to 20; Symptoms Checklist-90 (SCL-90) Depression Scale score greater than or equal to 28; SCL-90 Anxiety Scale Score greater than or equal to 18
2. Hormonal contraception use during the 1 cycle prior to the start study medication
3. Use of non-oral hormonal contraception in the 3 months prior to the screening
4. Total T value greater than 5 nmol/L at time of screening or at the pre-test vaginal photoplethysmograph (VPP) session
5. Androgen therapy during the 6 months prior to screening
6. Intention to become pregnant during the study
7. Lactation and/or pregnancy in the previous 6 months prior to screening
8. Any clinically significant abnormality following review of medical history, laboratory results and physical examination at screening
9. Treatment for any major psychiatric disorder in the previous 12 months or use of antidepressant medication prior to screening
10. Use of one or more of the following medications: psychoactive drugs, anti-hypertensive drugs, sex steroids other than the current OC
11. Present use or use within 30 days before the start of the study medication of the following drugs: hydantoins, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, troglitazone, felbamate, rifampicin, rifabutin, griseofulvin, nelfinavir, ritonavir and St John's wort (*Hypericum perforatum*)
12. Administration of any other investigational drug within 3 months prior to screening

**Date of first enrolment**

01/05/2007

**Date of final enrolment**

01/07/2009

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

**Meibergdreef 9**

Amsterdam

Netherlands

1105 AZ

# Sponsor information

## Organisation

Pantarhei Bioscience BV (Netherlands)

## Sponsor details

PO Box 464

Zeist

Netherlands

3700 AL

## Sponsor type

Industry

## Website

<http://www.pantarheibio.com/>

## ROR

<https://ror.org/03hagz796>

# Funder(s)

## Funder type

Industry

## Funder Name

Pantarhei Bioscience BV (Netherlands)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/07/2018   | 14/10/2019 | Yes            | No              |