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

Submission date	Recruitment status	[_] Prospectively registered
19/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/10/2019	Pregnancy and Childbirth	

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^2
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?
Results article	results	01/07/2018	14/10/2019	Yes	No