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Effects of concomitant treatment with an androgen on androgen metabolism, biochemical parameters, mood, fat, muscle and bone in women using an oral contraception

Submission date
20/11/2009

Recruitment status
No longer recruiting

Registration date
21/12/2009

Overall study status
Completed

Last Edited
20/05/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

PR3079

Study information

Scientific Title
A double-blind, placebo controlled, randomised, comparative, single-centre trial to assess the effects on the androgen metabolism and its effect on biochemical parameters, mood, fat, muscle and bone of continuous supplementation with an androgen in women using a monophasic contraception

Acronym
ARC-AMUSA study

Study objectives
To determine the effect of concomitant dehydroepiandrosterone (DHEA) compared to placebo in oral contraceptive (OC) users on androgen metabolism, biochemical parameters, mood, fat, muscle and bone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Comité d'Ethique of Centre Hospitalier Regional de la Citadelle, Liege, Belgium), 13/09/2007

Study design
Double-blind placebo-controlled randomised comparative single-centre trial

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

Treatment periods:
1. Run-in period, 3 cycles: DRSP/EE
2. Treatment period, 6 cycles: DRSP/EE and DHEA or placebo
3. Treatment extension, 7 cycles: DRSP/EE and DHEA or placebo

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Dehydroepiandrosterone, Yasmin® (drospirenone [DRSP], ethinyl estradiol [EE])

Primary outcome measure
1. Androgen metabolism: albumin, Tot T, sex hormone binding globulin (SHBG), dehydroepiandrosterone sulfate (DHEA-S), 4-androstenedione and 3 alpha androstanediol; calculated free thyroxine intake (FTI) and Free T
2. Oestradiol (E2)
3. Lipid metabolism: total cholesterol, high density liprprotein (HDL), low density lipoprotein (LDL) and triglycerides
4. Bone turn-over: serum osteocalcin and serum bone specific alkaline phosphatase (bone formation), serum CTX-I (bone resorption) and urine CTX-II (cartilage turnover)

All parameters measured at screening/baseline and at the end of cycle 3, 6, 9, 12 and 16.

Secondary outcome measures
1. General effect, satisfaction, health related quality of life, sexual functioning, menstrual symptoms and mood will be assessed by PRO instruments; measured at baseline and at the end of cycle 3, 6, 9 and 16
2. Body weight (weekly measurement)
3. Muscle, fat and bone: fat distribution (waist to hip ratio), percentage of fat mass, lean mass and bone mass, muscle strength (six muscles); measured at baseline and at the end of cycle 3, 9 and 16
4. Other endocrine parameters: fasting glucose, insulin, HbA1c, thyroid stimulating hormome (TSH), triiodothyronine (T3), cortisol, adrenocorticotropic hormone (ACTH); measured at screening/baseline and at the end of cycle 3, 9 and 16
5. Acceptability: discontinuation rates and reasons for discontinuations
6. Safety (vital signs, physical, gynaecological and breast examinations, safety lab, skin characteristics, bleeding data, [serious] adverse events, pregnancy), measured throughout the study

Overall study start date
01/11/2007

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Healthy females between 18 and 35 years of age who are in need for OC
2. No use of hormonal contraceptive treatment for at least 3 months prior to randomisation
3. Willing to use an OC for 9 subsequent cycles
4. Willing to have a documented spontaneous cycle for baseline observation without the use of any hormonal contraceptive treatment
5. Sexually active women
6. Regular menstrual cycle (24 - 35 days) prior to screening
7. Body mass index (BMI) between (greater than or equal to) 18 and (less than or equal to) 35 kg /m^2
8. Good physical and mental health
9. Sign a written informed consent agreement

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Contraindications for OC
2. Failure to ovulate during the documented spontaneous cycle for baseline observation
3. Use of hormonal contraceptive method during documented spontaneous cycle
4. Previous use of any hormonal contraceptive method during the last 3 months prior to randomisation
5. Use of any long term hormonal contraceptive method within 3 months after the limit of efficacy prior to screening
6. Androgen therapy during the 6 months prior to screening
7. Polycystic ovarian syndrome
8. Hyperandrogenism documented by free serum T value (greater than or equal to 9 pg/mL), severe acne and/or hirsutism at screening
9. No spontaneous menstruation has occurred following a delivery or abortion
10. Breastfeeding or within 2 months after stopping breastfeeding prior to the start of study medication and no spontaneous return of menstruation
11. Intention to become pregnant during the study
12. An abnormal cervical smear at screening
13. Any clinically significant abnormality following review of medical history, laboratory results and physical/gynaecological examination at screening
14. Treatment for any major psychiatric disorder in the previous 12 months or use of

antidepressant medication prior to screening
15. History of/or current (treated) skin disorder (e.g. acne) which might be influenced by the study treatment
16. Use of any relevant treatment for a skin disorder at the time of screening
17. Use of one or more of the following medications: psychoactive drugs, anti-hypertensive drugs
18. Present use or use within 30 days prior to the start of the study medication of the following drugs: phenytoin, barbiturates, primidone, carbamazapine, oxcarbazepine, topiramate, felbamate, rifampicin, nelfinavir, ritonavir, griseofulvin, ketoconazole, sex steroids (other than pre- and post-treatment contraceptive method) and herbal remedies containing Hypericum perforatum (St Johns Wort)
19. Administration of any other investigational drug within 3 months prior to screening

Date of first enrolment
01/11/2007

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
Belgium

Study participating centre
CHR Citadelle
Liege
Belgium
B-4000

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	01/02/2015		Yes	No