Study to investigate the effects of adding an androgen to oral contraception (OC) on mood disturbances experienced during OC use.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28672

Source
Nationaal Trial Register

Brief title
ARC-MOOD

Health condition

Mood disturbances during OC use

Sponsors and support

Primary sponsor: Pantarhei Bioscience
Source(s) of monetary or material Support: Pantharhei Bioscience

Intervention

Outcome measures

Primary outcome

Primary objective is to evaluate the effect of DHEA on mood disturbances during OC use

Secondary outcome

- To assess general effects on well-being

- To assess satisfaction and health related quality of life

Study description

Background summary

Design:

A double-blind, placebo-controlled, randomised N=1 study

Subjects:

Main group: Six healthy OC users who complain of mood disturbances during OC use only
Subgroup (optional): Six healthy women who have had complaints of severe mood disturbances during OC use only and are willing to use OC for 6 subsequent cycles (= 28 days per cycle)

Study Medication:

All participants will receive two tablets of study medication, which will be ingested daily during the first 21 days of every cycle. These tablets will either contain DHEA or placebo. During the pill-free period (day 22 – 28), there is no intake of study medication.

Total treatment duration:
6 cycles of 28 days each with a randomised monthly regimen (3 cycles placebo and 3 cycles DHEA)
All participants will continue using their regular OC.

Clinical phase
Phase II

Primary objective:

To evaluate the effect of DHEA on mood disturbances during OC use

Secondary objectives:

· To assess the general effects on well-being

· To assess satisfaction and health related quality of life

Endpoints:

· Daily mood rating (1-5)

· General effect of study medication on subject’s well-being over the past 3 weeks

· Satisfaction and health related quality of life over the past week of OC intake

Study design

6 cycles of 28 days per subject

Intervention

All participants will receive two tablets of study medication, which will be ingested daily during the first 21 days of every cycle. These tablets will either contain DHEA or placebo. During the pill-free period (day 22 – 28), there is no intake of study medication. Total treatment duration: 6 cycles of 28 days each with a randomised monthly regimen (3 cycles placebo and 3 cycles DHEA). All participants will continue using their regular OC.
The effect of concomitant DHEA compared to placebo in OC users on mood disturbances will be measured with a daily mood rating. This is a daily rating on a 5-point scale (1 meaning very negative, and 5 meaning very positive) included in the Study Diary.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women using oral contraceptives for at least 3 months prior to screening and aged 20-35 years (inclusive) (for subgroup: Women, aged 20-40 years (inclusive), using a non-hormonal contraceptive method for at least 3 months and willing to use an OC for 6 subsequent cycles).

2. Report of mood disturbances, and attributing this to OC use as evidenced by in depth interview independently performed by two investigators.

3. Regular menstrual cycles (24-35 days) prior to last start of OC use.

4. Body mass index between (≥) 18 and (≤) 35 kg/m2.

5. Good physical and mental health as judged by the Investigator determined by medical and gynaecological history, physical examination, clinical laboratory and vital signs.

6. Willing to give informed consent in writing.

Exclusion criteria

1. Use of non-oral hormonal contraception in the 3 months prior to the screening (for subgroup: Use of oral hormonal contraception in the 3 months prior to the screening).

2. Intention to become pregnant during the study.

3. Lactation and/or pregnancy in the previous 6 months prior to screening.

4. Any clinically significant abnormality following review of medical and gynaecological history, clinical laboratory (haematology, biochemistry and androgen parameters) and physical examination and vital signs.

5. Contraindications for contraceptive steroids.

6. Use of one or more of the following medications:

- Psychoactive drugs

- Antihypertensive drugs

- Sex steroids other than the current OC

- Use at present or within 30 days before start study medication:

hydantoins, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, troglitazone, felbamate, rifampicin, rifabutin, griseofulvin, nelfinavir, ritonavir and St. John’s wort (Hypericum perforatum)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2008
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	26-09-2008
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	NL1400
NTR-old	NTR1460
Other	Protocol nummer van Pantarhei Bioscience : PR3082
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A