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

Gepubliceerd: 26-09-2008 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28672

Bron
Nationaal Trial Register

Verkorte titel
ARC-MOOD

Aandoening

Mood disturbances during OC use

Ondersteuning

Primaire sponsor: Pantarhei Bioscience
Overige ondersteuning: Pantharhei Bioscience

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Onderzoeksopzet

6 cycles of 28 days per subject

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1400
NTR-old	NTR1460
Ander register	Protocol nummer van Pantarhei Bioscience : PR3082
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A