A dose finding study to assess contraceptive efficacy and the effect on liver function of estetrol contraception.

Gepubliceerd: 31-10-2009 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON27454

Bron
Nationaal Trial Register

Verkorte titel
Protocol PR3095

Aandoening

Hormonal contraceptive method

Ondersteuning

Primaire sponsor: Estetra S.A.
mw. X.Y. Zimmerman
p/a Postbus 464
3700 AL Zeist
Tel: +31 30 6 985 020
Fax: +31 30 6 985 021
yz@pantarheibio.com
Overige ondersteuning: Estetra S.A.
Rue du Travail, 16
4460 Grace-Hollogne
Belgique

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Follicle development will be measured in both ovaries by transvaginal ultrasound during the pre-treatment cycle, cycle 1 and cycle 3 on frequent timepoints during each cycle;
2. Liver parameters (carrier proteins, lipids, haemostasis, liver function, bone, glucose metabolism) will be measured at pre-treatment cycle, at the day 3 and 24 of cycle 1 and cycle 3, and at follow up visit.

Toelichting onderzoek

Achtergrond van het onderzoek

This is an open, parallel dose finding study in young, healthy, female volunteers of reproductive age.

The first primary objective of the study is to investigate the effect of 3 dosages of estetrol (E4) combined with a progestogen on suppression of ovarian follicular activity and ovulation inhibition. The second primary objective of the study is to assess the pharmacodynamic effect of 3 doses of E4 in combination with a progestogen on a broad range of biochemical liver parameters, known to be affected by the use of a COC.

Women who want to participate and who are using hormonal contraception, stop using their hormonal contraceptive after completing their pill strip and wait for their first spontaneous menstruation (i.e. after a wash-out cycle). Women who do not use hormonal contraception wait for their next menstruation. From the 9th (± 1) day after start of the menstruation onwards follicle growth will be monitored by ultrasonography once every 3 days (± 1) until ovulation occurs or until day 24 (± 1) after start of their menses (pre-treatment cycle). Women who ovulate within 24 (± 1) days after start of their menses will be eligible to participate. Treatment will start on the first day of their menses after the pre-treatment cycle. The women are randomized to one of six treatment groups. In each group approximately 18 subjects will be included. The subjects will be treated for 3 cycles of 24 days each followed by a 4 day pause.

During the pre-treatment and study period the activity of the hypothalamic-pituitary-ovarian (HPO) axis will be investigated by measuring follicular development using vaginal ultrasonography and by determining serum concentrations of Follicle Stimulating Hormone (FSH), Luteinising Hormone (LH), estradiol (E2), Progesterone (P), and testosterone (T).

Although the progestogen in COC inhibits ovulation when combined with EE, the effect on

ovarian suppression and ovulation inhibition of the E4 COC regimen has not been studied before. Therefore volunteers have to use a barrier method (eg. condoms) of contraception during the study. The subjects will have to complete a daily diary to monitor study drug compliance and vaginal bleeding.

Doel van het onderzoek

N/A

Onderzoeksopzet

3 treatment cycles; one cycle 28 days.

Onderzoeksproduct en/of interventie

Estetrol, in 3 different doses 5 mg E4, 10 mg E4 and 20 mg E4, each in combination with a progeston will be administered daily during three treatment cycles.

Contactpersonen

Publiek

Hanzeplein 1
C. Klipping
Groningen 9713 GZ
The Netherlands
+31 (0)50 361 09 99

Wetenschappelijk

Hanzeplein 1
C. Klipping
Groningen 9713 GZ
The Netherlands
+31 (0)50 361 09 99

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. At least 18 years and not older than 35 years of age;

2. Willing to use a barrier method of contraception during wash-out;

3. Women who ovulate in the pre-treatment cycle between day 9 and day 24;

4. Body mass index between 18 and 30 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. Both ovaries visible upon vaginal ultrasonography;

7. Willing to give informed consent in writing.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinically significant abnormal results of routine haematology, serum biocemistry, urinalysis and/or ECG;

2. Women with a washout cycle with a duration of more than 42 days;

3. Known or suspected pregnancy;

4. Lactation;

5. Pregnancy during accurate hormonal contraceptive use in the past;

6. Known or suspected breast cancer or a history of breast cancer;

7. Clinically significant abnormalities of the uterus and/or ovaries detected by examination and/or ultrasound;

8. A cervical smear with clinically relevant cytology with three years before study start;

9. Use of (hormonal) IUD within 2 months before screening;

10. Use of phytoestrogens;

11. Contraindications for contraceptive steroids;

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

A. Antihypertensive drugs;

B. Present use or within 2 cycles before start study medication: phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate, rifampicin, nelfinavir, ritonavir, griseofulvin, ketoconazole, sex steroids and St. John¡¯s wort (Hypericum perforatum).

13. Status post-partum or post-abortion within a period of 2 months before study start;

14. Administration of investigational drugs within 2 months before screening;

15. A history of (within 12 months) alcohol and drug abuse.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	02-11-2009
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	31-10-2009
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	NL1985
NTR-old	NTR2102
Ander register	Estetra S.A. : PR3095
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A