Effects of early luteal phase estrogen and progesterone administration on luteolysis in normo-ovulatory women.

No registrations found.

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

Summary

ID

NL-OMON22980

Source
NTR

Brief title
N/A

Health condition

The study will performed in healthy volunteers in order to get more insight in the mechanisms behind the insufficient luteal phase in patients treated with ovarian hyperstimulation for IVF.

Sponsors and support

Primary sponsor: N. Beckers, fertiliteitsarts, Room Hs 423, dr. Molewaterplein 40, 3015 GD Rotterdam. Tel: 010-4635738
Partially sponsored by Pantharhei
Source(s) of monetary or material Support: Partially sponsored by Pantharhei.

Intervention

Outcome measures

Primary outcome

Duration of the luteal phase. Every subject will undergo an end of trial visit. In this visit the subjects will hand over a paper on wich she will write down the onset of the menstuation. These data will be put into a excel database.

Secondary outcome

Endocrine profiles. Blood will be sampled every other day in the luteal phase from the day of the positive LH test until day LH+14.

Study description

Background summary

N/A

Study objective

The hypothesis will be tested that early luteal phase administration of high dosages of Estradiol and/or Progesterone in normo-ovulatory volunteers will reduce the luteal phase length.

Study design

N/A

Intervention

E2 group: 8 Fem 7 patches (Estradiol 0.1 mg/cm2 Merck BV, Amsterdam, the Netherlands) applied on the buttocks on the day of the observed LH surge combined with 4 puffs (600ìg) Aerdiol® (Estrogen 150 ìg/spray, Servier, Leiden, the Netherlands) every 3 hours on the day of LH. The patches were removed after the blood sampling on day LH+4.
P group: Prontogest i.m injections (Progesterone amp, 100 mg/ml, AMSA, Roma, Italia). Started on day LH+4: evening 25 mg; LH+5; morning 100 mg and evening 150 mg; LH+6: morning 300 mg and evening 300 mg.

E+P group: combination of above-mentioned regimens.

Non-treatment group; no medication.

Contacts

Public
Leids Universitair Medisch Centrum
Postbus 9600

J.T. Dissel, van
Leids Universitair Medisch Centrum
Afdeling Infectieziekten, C5P
Leiden 2300 RC
The Netherlands
+31715262613
Scientific
Leids Universitair Medisch Centrum
Postbus 9600

J.T. Dissel, van
Leids Universitair Medisch Centrum
Afdeling Infectieziekten, C5P
Leiden 2300 RC
The Netherlands
+31715262613

Eligibility criteria

Inclusion criteria

1. Regular menstrual cycle (25-34 days);

2. normal body weight (BMI 18-28);

3. normal reproductive age (20-37 yrs);

4. normal early follicular phase FSH levels.

Exclusion criteria

1. Known or suspected pregnancy;

2. the use of oral contraceptives (i.e. Provera®, Mirena®, Nuva ring® ect.) in the last three months;

3. smoking habit;

4. subjects suffering from epilepsy;

5. diabetes mellitus;

6. gastrointestinal, hepatic, renal, and/or pulmonary diseases;

7. abnormal history;

8. use of other investigational drugs within 3 months and/or use of hormonal preparations-other then dose used for COH-within 1 month prior to the start of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2003
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	02-11-2005
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	NL475
NTR-old	NTR516
Other	: VPG 03.01
ISRCTN	Incomplete data for ISRCTN

Study results

Summary results
Eur J Endocrinol. 2006 Aug;155(2):355-63.