Triptorelin Oral contraceptive Pill Flare-up in IVF/ICSI Treatment trial.

Gepubliceerd: 16-02-2011 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON29309

Bron
NTR

Verkorte titel
TOPFIT trial

Aandoening

LH surge, ovulation, sub-fertility, GnRH-agonist, GnRH-antagonist

Ondersteuning

Primaire sponsor: VU University Medical Center, Department of Obstetrics and Gynaecology
Overige ondersteuning: VU University Medical Center, Department of Obstetrics and Gynaecology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess non-inferiority of the short, flare-up GnRH-agonist protocol compared to the GnRH-antagonist protocol, both with OC pill pre-treatment, with respect to incidence of premature serum LH surges, with or without a rise in progesterone, in patients treated with IVF/ICSI for subfertility.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

26-Apr-2013: Trial has ended prematurely due to a inclusion shortage.

Doel van het onderzoek

The aim of the study is to show non-inferiority of a short, flare-up GnRH-agonist protocol to the GnRH-antagonist protocol, both with OC pill pre-treatment, in women undergoing in vitro fertilisation (IVF) or intracellular sperm injection (ICSI) treatment with gonadotrophins.

Onderzoeksopzet

The primary endpoint is the incidence of premature LH surges, defined as a serum LH value > 10 IU/l, with or without a rise in progesterone, defined as a value > 1 ng/ml (> 3.18 nmol/l).

Secondary endpoints include incidence of premature urine LH surges, follicular development, number of oocytes and (top-quality) embryo’s, embryo metabolomics, endometrial thickness, hormone levels (LH, FSH, oestradiol, progesterone), (signs of) ovarian hyperstimulation syndrome (OHSS), cancellation rate, fertilisation rate, implantation rate, ongoing pregnancy rate and live birth rate. In addition, (hypo-oestrogenic) adverse events and total dose and duration of GnRH analogue and gonadotrophin treatment will be assessed.

Onderzoeksproduct en/of interventie

1. Flare-up GnRH-agonist protocol with OC pill pre-treatment. OC pill is given during 21±3 days of the preceding cycle. On day two of the menses after withdrawal of the OC pill of the following cycle, triptorelin is started, accompanied at day three by HP-hMG in a fixed dose of 150 IU. Both are given until criteria for hCG administration are met;

2. GnRH-antagonist protocol with OC pill pre-treatment. OC pill is given during 21±3 days of the preceding cycle. On day three of the menses of the following cycle, HP-hMG (fixed dose of 150 IU) is started and accompanied by cetrorelix at day six of gonadotrophin administration, both given until criteria for hCG administration are met.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Any woman undergoing IVF/ICSI treatment (first, second or third cycle) is eligible to participate in the trial. A patient can only participate once in the study. Signed informed consent is mandatory.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women aged over 39 years;

2. Women with a single ovary;

3. Known poor responders, defined as women with a follicle count of < 4 follicles > 14 mm in a previous IVF/ICSI treatment cycle;

4. History or evidence of polycystic ovary syndrome (PCOS) or incipient ovarian failure;

5. Severe endometriosis, stage III/IV, needing Surrey stimulation protocol;

6. Women with known contraindications for oral OCs.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	16-02-2011
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	NL2631
NTR-old	NTR2759
Ander register	METc VUmc : 2010/118
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A