Mild ovarian stimulation in women with poor ovarian response undergoing IVF and ICSI.

Gepubliceerd: 10-11-2010 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26313

Bron
NTR

Verkorte titel
PRIMA

Aandoening

Poor ovarian response; mild ovarian stimulation; IVF;ICSI

Ondersteuning

Primaire sponsor: Non
Overige ondersteuning: Non

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ongoing pregnancy (OPR) per women randomised (defined as a viable pregnancy of at least 10 weeks of gestation).

Toelichting onderzoek

Achtergrond van het onderzoek

To compare mild ovarian stimulation IVF versus the standard IVF followed by replacement embryos one cycle cryopreserved embryo in poor responders women. Couples are allocated 1:1 to a treatment consisting of one cycle of mild ovarian stimulation IVF-ET plus subsequent cryo-cycles or one cycle of conventional controlled ovarian hyperstimulation IVF-ET followed by plus subsequent cryo-cycles. The randomisation is performed by computer at a central randomisation center at the IVF center.

Doel van het onderzoek

the aim of this study is to compare two strategies that present a large contrast in the stimulation dosage, i.e. a high dosage of stimulation versus a low dosage of stimulation. Our study is designed to objectively compare the ongoing pregnancy rate of mild stimulation, i.e. a GnRH antagonist short protocol with 150 IU FSH preceded by OCP (mild ovarian stimulation IVF) to a long GnRH agonist protocol with 450 IU HMG,(standard IVF), followed by replacement of two embryos in expected and non expected poor responder women. Subsequent cryopreserved transfer cycles will be included in the analysis. Expected and unexpected poor responder women will be analysed separately

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Group (1) will be pre-treated with oral contraceptive pills (OCP) started on cycle day 2-3 of the preceding cycle for a variable period of 14-21 days. The date of the last OC intake will be decided by the investigator , then a fixed dose of 150IU/day HP/rec FSH, sc will be initiated on day 5 after the last OCP after establishing ovarian and uterine quiescence using vaginal ultrasound. GnRH antagonist will be commenced on stimulation day 6 (Fixed protocol).

Group (2) will be treated with the GnRH agonist triptoreline starting 1 wk before the expected menses (usually cycle d 21). After down-regulation is achieved [serum estradiol (E2), 150 pmol/liter], ovarian stimulation will be commenced with a fixed daily dose of 450 IU/day HMG. After establishing ovarian and uterine quiescence using vaginal ultrasound, Triptoreline and GnRH agonist will be continued up to and including the day of human chorionic gonadotropin (HCG) administration. When the leading follicle reaches a diameter of 18 mm or more and at

least two follicles reach a diameter of 15 mm or more, HP/rec FSH will be stopped, and a single sc bolus of 10,000 IU hCG (Pregnyl, NV Organon, Oss, The Netherlands) will be administered 35 h before the planned time of oocyte retrieval. All follicles 12 mm or larger will be aspirated. Subsequently, IVF with or without ICSI will be performed, after that the DET will be performed 3,5 d thereafter. TET is allowed in case of patients are more than 40 years or in patients with poor embryo quality. Any remaining good-quality embryos are cryopreserved using slow-cooling on day 4 and transferred in subsequent cycles until pregnancy is achieved or all embryos have been used. Luteal support in the form of intravaginal progesterone (P; Progestan, Organon; 200 mg, three times daily) will be given from the day of oocyte retrieval until a urine pregnancy test will be performed 17 d later. In case of a positive pregnancy test women will be monitored using ultrasound visualisation during their pregnancy. Monitoring will take place at 5 to 8 weeks of amenorrhea to check whether an intrauterine gestational sac is present, i.e. a clinical pregnancy. Subsequently monitoring will take place at 11 to 12 weeks amenorrhea to register the presence of an intrauterine gestational sac with fetal heart beat, i.e. an ongoing pregnancy.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Valid indication for IVF or ICSI;

2. Patients with expected or non expected poor response:

A. Expected:

i. Aged women > 35 years;

ii. And/or women who have a raised basal day 3 FSH level > 10 IU/mL irrespective of age;

iii. And/or women who have a low antral follicular count < 5 follicles.

B. Unexpected:

i. Women aged < 35 years old;

ii. And/or women who responded poorly during their first IVF cycle i.e. total gonadotrophin dose used > 3000 IU FSH for follicle growth;

iii. And/or women who have low oocyte yield < 3-5 follicles despite high daily stimulation dose;

iiii. And/or women who have their IVF cycle cancelled due to a low estradiol level < 300-850 pg/ml.

3. Pre-wash total motile sperm count above 10 million or a post-wash total motile sperm count above 1 million.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women > 43 years old;

2. Polycystic ovary syndrome or any other anovulation;

3. Endocrino pathological disease like: Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, imminent ovarian failure, premature ovarian failure, hypothalamic amenorrhea, hypothyroid, diabetes mellitus type;

4. If not willing or able to sign the consent form.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-11-2010
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-11-2010
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	NL2477
NTR-old	NTR2593
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A