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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26313

Source
NTR

Brief title
PRIMA

Health condition

Poor ovarian response; mild ovarian stimulation; IVF;ICSI

Sponsors and support

Primary sponsor: Non
Source(s) of monetary or material Support: Non

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Clinical pregnancy, defined as any registered embryonic heartbeat at sonography;

2. Biochemical pregnancy ((defined as an increase in serum HCG or a positive pregnancy test);

3. Multiple pregnancy, defined as registered heartbeat of at least two foetuses at 6-8 weeks of gestation;

4. Miscarriage rate;

5. Fertilization rate;

6. Number of oocytes;

7. Number of metaphase II oocytes;

8. Number of embryos;

9. Number of ET;

10. Number of embryos frozen;

11. Total FSH dose used for ovarian stimulation;

12. Cancellation rate;

13. Drop-out rate;

14. Costs.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-11-2010
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-11-2010
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	NL2477
NTR-old	NTR2593
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A