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

No registrations found.

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

Summary

ID

NL-OMON29309

Source
NTR

Brief title
TOPFIT trial

Health condition

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

Sponsors and support

Primary sponsor: VU University Medical Center, Department of Obstetrics and Gynaecology
Source(s) of monetary or material Support: VU University Medical Center, Department of Obstetrics and Gynaecology

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To assess non-inferiority of the short, flare-up GnRH-agonist protocol compared to the GnRH-antagonist protocol, both with OC pill pre-treatment, in patients treated with IVF/ICSI for subfertility, with respect to:

1. Premature urinary LH surges;

2. Follicular development;

3. Number of oocytes and (top-quality) embryos;

4. Embryo metabolomics;

5. Endometrial thickness;

6. Hormone levels: LH, FSH, oestradiol, progesterone;

7. (Signs of) OHSS;

8. Cancellation rate;

9. Fertilisation rate, implantation rate, ongoing pregnancy rate and live birth rate;

10. (Hypo-oestrogenic) adverse events;

11. Total dose and duration of GnRH analogue and gonadotrophin treatment.

Study description

Background summary

N/A

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

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2011

Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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

Study results

Summary results
N/A