OPTIMisation of cost effectiveness through Individualised FSH Stimulation dosages for IVF Treatment: A randomised trial.

No registrations found.

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

Summary

ID

NL-OMON27790

Source
Nationaal Trial Register

Brief title
OPTIMIST

Health condition

IVF/ICSI
Infertility
Ovarian reserve test
Antral follicle count (AFC)
Individualized FSH regimen

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

1. Ongoing pregnancy resulting in live birth within 18 months after randomisation. These pregnancies can be obtained in treatment cycles with fresh embryos, as well as in SUBSEQUENT CRYO/THAW CYCLES after completion of any fresh stimulation cycle. Spontaneous pregnancies between treatment cycles will also be taken into account;

2. Costs of treatment: Direct medical costs, direct non-medical costs and indirect costs.

Secondary outcome

1. Number of oocytes;

2. Poor response (less than 5 oocytes at retrieval or cancellation due to insufficient follicle growth, i.e. less than 2 dominant follicles sized more than 12 mm growing);
3. Hyper response (more than 15 oocytes at retrieval or cancellation due to excessive response, i.e. > 20 follicles sized > 12 mm with an estradiol above 11.700 pmol/L OR > 30 follicles sized > 12 mm growing);
4. OHSS grade 2 or 3;
5. Cycle cancellation for hyper and poor response, multiple pregnancy, total IU of FSH applied per stimulation cycle, number of cycles needed per live birth, prevalence of abnormal ORT in subfertile women.

Study description

Background summary

Rationale:

IVF is a very costly treatment due to the use of gonadotropins (FSH). In current clinical practice FSH is usually given in a standard dose. However, due to differences in ovarian reserve between women, the ovarian responses also differ, with negative consequences on pregnancy rates. In the last decade, ovarian reserve tests (ORT) are frequently performed prior to IVF, without consensus on the translation to FSH dose and without a systematic evaluation of its costs and effects. We hypothesize that in women undergoing IVF, an individualized dose regimen for FSH, based on an ORT is more cost-effective, but this has never been assessed.
Objective: To evaluate whether in an IVF program routine application of an ORT and a subsequent individualised FSH regimen is cost-effective, compared to a standard dose regimen.

Study design:

Cohort study in which all women scheduled for IVF undergo ORT. Women with a predicted poor or high ovarian response will be randomised between the individualised FSH regimen and the standard dose regimen.
Study population: All women scheduled for a first IVF or ICSI treatment.

Intervention:

All women will undergo assessment of their ovarian reserve using the Antral Follicle Count (AFC) for prediction of poor response or high response. Women with a predicted poor response will be randomised for an increased FSH dosage or standard dosage (150 IU/d), whereas women with a predicted hyperresponse will be randomised for a decreased FSH dosage or standard dosage (150 IU/d).

Main study parameters/endpoints:

The primary outcome will be live birth. Secondary outcomes will be poor ovarian response, hyperresponse, cycle cancellation rates, number of cycles needed per live birth and costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients who are screened for ovarian response prediction will undergo a transvaginal ultrasonography for antral follicle counting and a single blood sampling. They will often not have to pay one extra hospital visit to undergo these investigations, as in preIVF work up these investigations will be incorporated.

Study objective

To evaluate whether in an IVF program routine application of an ovarian reserve test (ORT) and a subsequent individualised FSH regimen is cost-effective compared to a standard dose regimen.

Study design

Ongoing pregnancy resulting in live birth within 18 months after randomisation.

Intervention

Patients with predicted poor response (AFC below 101) on the ORT will be randomly allocated to a treatment strategy based on an increased FSH dose versus standard FSH dose. In case they are randomised to dose adjustment they will start with 450 IU of FSH/day in case the AFC is below 78, and with 225 IU if the AFC is 78-10.

Patients with predicted hyper response (AFC more than 15) will be randomly allocated to a treatment strategy based on decreased FSH dose versus standard FSH dose. In case they are randomised to dose adjustment they will start with 100 IU of FSH/day.

Contacts

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Eligibility criteria

Inclusion criteria

1. Regular indication for IVF or IVF-ICSI;

2. Female age < 44 years;

3. Regular cycle (average length 25-35 days);

4. No major uterine or ovarian abnormalities detected at TVS;

5. No previous IVF cycles;

6. Written informed consent.

Exclusion criteria

1. Oocyte donation;

2. Medical contra indication for pregnancy or IVF treatment;

3. Polycystic Ovary Syndrome (PCOS);

4. Endocrine or metabolic abnormalities (pituitary, adrenal, pancreas, liver or kidney).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	1500
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-12-2010

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	NL2539
NTR-old	NTR2657
Other	METC UMC Utrecht : 10-273
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A