Optimisation of cost effectiveness through Individualised FSH Stimulation dosages for IVF Treatment: The OPTIMIST trial.

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38129

Source
ToetsingOnline

Brief title
The OPTIMIST trial

Condition

- Reproductive tract disorders NEC

Synonym
Infertility, Subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW,Roche Diagnostics GmbH

Intervention

Keyword: AFC, Dosage, FSH, Ovarian Reserve

Outcome measures

Primary outcome

The primary outcome will be live birth and costs based on previous calculations

of the various study procedures

Secondary outcome

Secondary outcomes will be poor ovarian response, hyperresponse, cycle

cancellation rates, number of cycles needed per live birth.

Study description

Background summary

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 response also differs with negative consequences on pregnancy rates. In the last decade ovarian reserve tests (ORT) have frequently been 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.

Study 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.

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).

Study burden and risks

Burden and risks do not differ from routinely applied IVF treatment

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Regular indication for IVF or IVF-ICSI
- Female age < 44 years
- Regular cycle (average length 25-35 days)
- No major uterine or ovarian abnormalities detected at TVS
- No previous IVF cycles or first IVF cycle after birth of a child
- Written informed consent

Exclusion criteria

- Oocyte donation
- Medical contra indication for pregnancy or IVF treatment
- Polycystic Ovary Syndrome (PCOS)
- Untreated 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2011
Enrollment:	1500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-02-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2010-023879-25-NL
CCMO	NL32902.041.11
Other	NTR TC = 2657