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

Published: 07-02-2011 Last updated: 27-04-2024

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

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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

Public

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Scientific

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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