The effect on embryo-quality of rLH-addition to rFSH for controlled ovarian hyperstimulation in women with poor ovarian reserve

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The effect of rLH for controlled ovarian hyperstimulation in order to achieve an increase of 10% in top quality embryos.

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON31586

Source
ToetsingOnline

Brief title
L-age study

Condition

- Endocrine disorders of gonadal function
- Sexual function and fertility disorders

Synonym
subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,farmaceutische industrie,Serono

Intervention

Keyword: fertilization in vitro, luteinizing hormone, ovarian failure

Outcome measures

Primary outcome

Primary outcome: Percentage of top-quality embryos

Secondary outcome

Secondary outcome

Number of follicles > 14 mm on hCG day

Number of retrieved oocytes

Number of metaphase II oocytes

Pronuclear morphology

Total number of embryos

Presence of early cleavage

Cleavage stage morphology

Number of embryos suitable for transfer

Biochemical, clinical, ongoing pregnancies

Live-birth rate

Study description

Background summary

LH is known to play a role in oocyte growth and maturation it may subsequently play a relevant role in optimizing fertilization and embryo competence. On the one hand we know that older women have less competent embryos, and on the other

hand we know that LH can have a beneficial effect on embryo-quality. We therefore want to explore the beneficial effect of adding rLH to rFSH for controlled ovarian hyperstimulation in IVF of ICSI, compared to rFSH alone.

Study objective

The effect of rLH for controlled ovarian hyperstimulation in order to achieve an increase of 10% in top quality embryos.

Study design

Randomized, clinical study in 220 women from 35 years of age and women with IOF undergoing IVF/ICSI

Intervention

Controlled Ovarian Hyperstimulation in a GnRH agonist long luteal protocol with
(1) 300 rFSH sc daily alone or
(2) 2:1 ratio rFSH : rLH i.e. 300 IU/L rFSH and 150 IU/L rLH sc
Followed by a standard IVF or ICSI procedure.
The obtained embryo's will be classified on morfology by a computer program called Fertimorf.

Study burden and risks

No risk, other then the risk an IVF/ICSI procedure entails.

Contacts

Public
Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women are eligible if the following apply:
1. Patients between 35 and 43 years of age
2. Patients with IOF, <35 years
3. Valid indication for IVF or ICSI
4. Undergoing IVF/ICSI first oocyte retrieval

Exclusion criteria

A woman must not be entered if any of the following apply:
1. Endocrinopathological disease as: Cushing*s syndrome, adrenal hyperplasia, hyperprolactinaemia, acromegaly, hypothalamic amenorrhea, hypothyroidy, diabetes mellitus type I, PCOS
2. If not willing or able to sign the informed consent form

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:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	220
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	follitropin alpha, brand name Gonal-F
Generic name:	recombinant FSH
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	lutropin alpha, brand name luveris
Generic name:	recombinant LH
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2007-007487-22-NL
CCMO	NL20406.018.08