Among IVF patients undergoing fixed antagonist protocols with recombinant FSH, does administration of recombinant FSH from cycle day 5 onwards compared with cycle day 2 onwards, yield a higher number of good quality embryos?

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The aim of the study is to determine whether cycle day (CD) 5 start of stimulation will lead to better quality of embryos, based on morphology, than CD 2 start, in IVF with GnRH antagonist co-treatment started on a fixed day.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON33540

Source
ToetsingOnline

Brief title
Comparing start stimulation cycle day 2 versus cycle day 5 in IVF

Condition

- Sexual function and fertility disorders

Synonym
Ovarium stimulation IVF treatment

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: controlled ovarian stimulation, cycle day 2 vs 5, GnRH antagonist, IVF

Outcome measures

Primary outcome

Primary outcome parameter is number of top embryos per ovum pick up.

Secondary outcome

Secondary outcome measures are duration of stimulation, cancellation rate, fertilization rate, number of cumulus oocyte complexes obtained, number of mature oocytes obtained, number of top embryos per started cycle, amount of IU recFSH, implantation rates in high responders, endocrine changes (FSH, Oestradiol, Progesteron, LH, AMH) and clinical pregnancy rate.

Study description

Background summary

Milder stimulation protocols have the advantage of being less expensive and more patient-friendly. Moreover, recent evidence suggests that mild stimulation protocols lead to lower embryo aneuploidy rates compared to conventional treatment regimens. Although with mild stimulation protocols the expected number of oocytes retrieved will be lower, pregnancy rates have shown to be similar possibly because embryo quality outfavours embryo quantity.

Study objective

The aim of the study is to determine whether cycle day (CD) 5 start of stimulation will lead to better quality of embryos, based on morphology, than

CD 2 start, in IVF with GnRH antagonist co-treatment started on a fixed day.

Study design

Prospective randomized trial comparing two different starting days of ovariumstimualtion (day 2 versus day 5) for IVF treatment.

Intervention

One group wil start on cycle day 2 with stimulation of the ovari with recombinant FSH. The other group will start on cycle day 5. Both group will start suppressing the gonadotrophin production of the the pituitary gland on cycle day 6 with a GnRH antagonist.

Study burden and risks

Patients will visit the hospital for performing an ultrasound and blood samples. This probably will be ones or twices more than during a standard IVF treatment.
The risks will be comparable with the standard IVF treatment; risk of infection, bleeding, or ovarium hyperstimulation syndrome. De side effects of the medication are the same as in the standard IVF treatment.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female age < 39 years
FSH < 12 IU/l
BMI 18-29 kg/m2
Regular cycle (25-35 days)
No major uterine or ovarian abnormalities
No previous IVF cycles
Written informed consent

Exclusion criteria

Oocyte donation
Medical contra indication for pregnancy or IVF treatment
Endometriosis >= grade 3
Polycystic Ovarium Syndrome (PCOS)
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):	23-02-2009
Enrollment:	117
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Puregon
Generic name:	Beta Follitropin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-09-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-12-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	24-03-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-12-2009
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2008-005261-57-NL
CCMO	NL23705.041.08