FSH receptor polymorphisms and treatment of poor responders

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

Summary

ID

NL-OMON31719

Source
ToetsingOnline

Brief title
FSH receptor polymorphisms and treatment of poor responders

Condition

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

Synonym
poor response in assisted reproduction techniques (IVF/ICSI)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Wetenschappelijk Onderzoek Gynaecologie (SWOG)

Intervention

Keyword: FSH receptor polymorphism, ovarian stimulation protocols, poor responders

Outcome measures

Primary outcome

-The FSH receptor polymorphism genotype.

-The number of growing follicles and retrieved oocytes per treatment cycle.

Secondary outcome

Not applicable.

Study description

Background summary

A poor response to FSH stimulation in IVF or ICSI, implicates either limited ovarian reserve or relative insensitivity of the ovary to FSH. In particular with a less sensitive ovary some benefit may be expected from a dose increase of FSH in a next cycle. We aim to research whether it is useful to stimulate poor responders with a higher dosage of FSH in a short protocol when they have a presumed less sensitive FSH receptor polymorphism genotype.

Study objective

The hypothesis is that women who have the Ser680Ser (SS) variant of the FSH receptor genotype, in comparison with women with the Ser680Asn (NS) or Asn680Asn (NN) variant, are less sensitive to FSH and because of that need higher dosages of FSH when they are treated for subfertility.
This could confirm a predictor function of the FSH receptor polymorphism genotyping in the treatment of poor responders.

Study design

Retrospective chart review. Pilot study for a future prospective study.

Study burden and risks

-One blood sample, taken in the clinic or at home

-No risk and no direct benefit for the patient however future subfertility patients may benefit from the outcome of this study.

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

Inclusion criteria are 2 ovaries in situ, less than 1,5 years between the two treatments, the use of a GnRH-agonist in the short protocol using 450 units of FSH, a minimum of one previous IVF or ICSI cycle in which the dosage FSH was less than 450 units of FSH (i.e. 225 or 300 IU/day), a long suppression protocol and a GnRH-agonist was used.

Exclusion criteria

Exclusion criteria are removal of one ovary, more than 1,5 years between the treatments, the use of a GnRH-antagonist and no previous IVF/ ICSI cycle(s) or previous cycles in which the dosage was also 450 units of FSH or a short protocol was used.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	112
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-03-2008
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
CCMO	NL18880.029.07