Assessing the course of psychological emotions and endocrine stress response from the start of the ovarian stimulated period up to the first pregnancy test result in a randomized clinical trial comparing two fertility treatments.

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To evaluate the course of psychological emotions, from the active treatment period until the first pregnancy test result, in IVF patients participating in a randomized controlled trial comparing two different IVF treatments (ENDO-RECEPT).

Ethical review	Approved WMO
Status	Pending
Health condition type	Sexual function and fertility disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38848

Source
ToetsingOnline

Brief title
ENDORECEPT - COPE

Condition

- Sexual function and fertility disorders

Synonym
Psychological distress in ivf treatments

Research involving

Human

Sponsors and support

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

Intervention

Keyword: IVF / ICSI, psychology, stress

Outcome measures

Primary outcome

The differences in course of psychological emotions, e.g. different elevated

levels of anxiety or different levels of anxiety at different time points

during two different IVF treatments, especially at oocyte retrieval and

pregnancy testing.

Secondary outcome

The secondary outcome is stress in relation to pregnancy outcome.

Study description

Background summary

In vitro fertilization (IVF) treatments are psychologically and emotionally stressful. Little research has been carried out to document the psychological processes that unfold during IVF treatments. Most randomized clinical randomized trials are focused on the primary medical outcome. The aim of the present study is to document the course of psychological emotions like anxiety, depression, positive affect and coping from the start of the ovarian stimulated period up to the first pregnancy test result in two different fertility treatments. Daily emotional reactions (e.g., anxiety, depression and positive affect) and coping during active treatment, and the waiting time up to whether pregnancy was achieved will be monitored using a daily record-keeping checklist designed for fertility treatment.

Study objective

To evaluate the course of psychological emotions, from the active treatment period until the first pregnancy test result, in IVF patients participating in a randomized controlled trial comparing two different IVF treatments (ENDO-RECEPT).

Study design

This study is a prospective cohort study.

Daily emotions (i.e. anxiety, depression and positive affect) will be documented during the active phase of the fertility treatment using daily record keeping checklists. These checklists are designed specifically for patients undergoing fertility treatments. In addition, we will measure the cortisol levels from saliva samples at four different time points during the treatment.

Study burden and risks

The burden of participation equals the filling out of a short daily record keeping checklist during either seven or eleven weeks depending on the allocation for treatment and five mornings of saliva sampling. Participation to this study has no increased risks for the couples undergoing in vitro fertilization treatment. The benefit to the couple is the expected increased insight in the experienced distress during in vitro fertilization treatments. Healthcare professionals can assist their patients by facilitating coping strategies that better fit the demands of the IVF/ICSI treatment and by offering support once outcomes are known.

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

All patients that are participating in the ENDO-RECEPT trial

Exclusion criteria

Patients that are not willing to sign the informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	150

Type:	Anticipated

Ethics review

Approved WMO Date:	06-08-2013
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL44651.000.13