A single-center non-blinded randomized controlled trial on the effect of ovarian hyperstimulation on endometrial receptivity.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24197

Source
Nationaal Trial Register

Brief title
ENDO-RECEPT

Health condition

Subfertility or infertility

Sponsors and support

Primary sponsor: Zorgonderzoek Nederland (ZonMw)
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be cumulative ongoing pregnancy rate per cycle after twelve

months of treatment.

Secondary outcome

Secondary outcome measures will be embryo quality, clinical pregnancy rate, miscarriage rate, live birth rate, time to pregnancy, birth weight and percentage of children with congenital abnormalities.

Study description

Background summary

Ovarian hyperstimulation is used in IVF/ICSI cycles to retrieve multiple oocytes. The downside of ovarian hyperstimulation is that it negatively impacts endometrial receptivity. The ENDO-RECEPT study investigates whether disengagement of embryo transfer from ovarian hyperstimulation leads to an improved ongoing pregnancy rate as compared to the standard treatment of fresh embryo transfer in a stimulated cycle.

Study objective

To investigate whether disengagement of embryo transfer from ovarian hyperstimulation leads to higher ongoing pregnancy rates.

Study design

The duration of the study is 2.25 years.

Intervention

Ovarian hyperstimulation, oocyte retrieval and oocyte fertilization will be performed using standard procedures.

In the control arm, one or two fresh embryo(s) will be transferred in the same cycle with cryopreservation of all supernumerary embryos and subsequent transfer of frozen/thawed embryos in artificial cycles if pregnancy is not achieved after fresh transfer.

In the experimental arm, all embryos will be cryopreserved for subsequent transfer in artificial cycles.

Contacts

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Eligibility criteria

Inclusion criteria

Subfertile couples with female age <43 undergoing IVF (in vitro fertilization) or ICSI (intracytoplasmatic sperm injection).

Exclusion criteria

1. Couples undergoing a PGD cycle;

2. Couples for which IVF/ICSI is used to prevent the transmission of HIV;

3. Couples undergoing a modified natural cycle;

5. Women with borderline or invasive ovarian cancer;

6. Women with contraindications for IVF/ICSI treatment such as cardiovascular-pulmonary disease, severe diabetes, bleeding disorders, immunodeficiency and morbid obesity;

7. Women with premature ovarian failure;

8. Women with severe psychopathology, severe anxiety and inability to cope with treatment;

9. Not able or willing to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	193
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	09-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38364
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3039
NTR-old	NTR3187
CCMO	NL37056.000.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38364

Study results

Summary results
N/A