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

Published: 18-10-2012
Last updated: 19-03-2025

To compare the cumulative ongoing pregnancy rate after transfer of frozen/thawed embryos in a cycle without ovarian hyperstimulation with transfer of fresh embryos in a cycle with ovarian hyperstimulation.

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

Summary

ID

NL-OMON38364

Source
ToetsingOnline

Brief title
ENDO-RECEPT

Condition

- 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: ZonMw

Intervention

Keyword: embryo transfer, Infertility, IVF

Outcome measures

Primary outcome

Ongoing pregnancy defined by the presence of a viable intra-uterine pregnancy

at 12 weeks of gestation.

Secondary outcome

Secondary outcomes are embryo quality, implantation rate, biochemical

pregnancy, clinical pregnancy, multiple pregnancies, live birth, time to

pregnancy, health of babies born and costs.

Study description

Background summary

The chance of embryo implantation with IVF/ICSI is, unfortunately, still disappointingly low. Only 25% of couples undergoing IVF/ICSI conceive. IVF/ICSI cycles are characterized by ovarian hyperstimulation to obtain multiple oocytes for in vitro fertilization. However, ovarian hyperstimulation does not only cause more oocytes but also causes changes in the endometrium hampering endometrial receptivity thereby creating suboptimal implantation chances. We aim to improve the ongoing pregnancy rates in IVF/ICSI cycles by disengagement of ovarian hyperstimulation and embryo transfer.

Study objective

To compare the cumulative ongoing pregnancy rate after transfer of frozen/thawed embryos in a cycle without ovarian hyperstimulation with transfer of fresh embryos in a cycle with ovarian hyperstimulation.

Study design

Randomised comparison of transfer of frozen/thawed embryos in cycles without

ovarian hyperstimulation (disengagement strategy) versus transfer of fresh embryos in cycles with ovarian hyperstimulation (standard strategy).

Intervention

Ovarian hyperstimulation, oocyte retrieval and oocyte fertilization will be performed using standard procedures. In the control arm one or two fresh embryos will be transferred in the same cycle and supernumerary embryos of sufficient quality will be cryopreserved and subsequentely transferred in a cycle without ovarian hyperstimulation after thawing when pregnancy is not achieved after fresh transfer. In the experimental arm, all embryos of sufficient quality will be cryopreserved and transferred after thawing in cycles without ovarian hyperstimulation .

Study burden and risks

The burden of participation equals the burden of a standard IVF/ICSI cycle, i.e. a 3-week period with controlled ovarian hormonal stimulation, ultrasound monitoring (4-5 times), endocrine monitoring (4-5 times) and transvaginal follicle aspiration. The risks to the women are limited to the risks associated with the IVF/ICSI procedure such as ovarian hyperstimulation syndrome and infection. The benefit to the couple is the expected increased chance to achieve a pregnancy.

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 couples that present to one of the participating centers for their first IVF/ICSI treatment.

Exclusion criteria

1.Women younger than 18 and older than 38year
2. Couples undergoing a PGD cycle.
3. Couples for which IVF/ICSI is used to prevent the transmission of HIV.
4. Couples undergoing a modified natural cycle.
5. Couples undergoing IVF/ICSI with surgically retrieved spermatozoa.
6. Women with borderline or invasive ovarian cancer.
7. Women with contraindications for IVF/ICSI treatment such as cardiovascular-pulmonary disease, severe diabetes, bleeding disorders, immunodeficiency and morbid obesity
8. Women with premature ovarian failure.
9. Women with severe psychopathology, severe anxiety and inability to cope with treatment.
10. 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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	193
Type:	Anticipated

Ethics review

Approved WMO Date:	18-10-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	24-09-2013
Application type:	Amendment
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

ID: 24197
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37056.000.11
Other	NTR 3187(Dutch Trail Register)
OMON	NL-OMON24197