The freeze-all strategy in IVF: who benefits?

Published: 08-07-2015
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To test the hypothesis that in women undergoing IVF/ICSI a freeze-all strategy results in higher ongoing pregnancy rates and is more cost-effective compared to a fresh embryo transfer.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON42754

Source
ToetsingOnline

Brief title
Freeze-all

Condition

- Sexual function and fertility disorders

Synonym
infertility, subfertility

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: endometrium, IVF, progesterone, thawed embryo

Outcome measures

Primary outcome

Ongoing pregnancy rate per woman and progesterone serum level at day of

ovulation trigger.

Secondary outcome

1. multiple ongoing pregnancy rates

2. live birth rates

3. cumulative ongoing pregnancy rates

4. time to pregnancy

5. costs

6. health-related quality of life (HRQL)

7. embryologic parameters: morphology, implantation rate

8. freeze-thaw survival per centre

9. endometrial parameters: thickness, appearance

Study description

Background summary

Ovarian hyperstimulation does not only lead to the maturation of multiple oocytes but also causes changes in the endometrium that hamper endometrium receptivity thereby creating suboptimal implantation chances for the transferred embryo. Disengagement of the ovarian hyperstimulation from the embryo transfer by freezing all embryos followed by a transfer in a subsequent unstimulated cycle, overcomes this problem. It is not known which women benefit most from disengagement.

Study objective

To test the hypothesis that in women undergoing IVF/ICSI a freeze-all strategy results in higher ongoing pregnancy rates and is more cost-effective compared to a fresh embryo transfer.

Study design

multicentre marker-RCT with a cost-effectiveness analysis.

Intervention

Cryopreservation of all embryos at day 3-4 and postponed first transfer of the embryo in an unstimulated cycle. Cryopreservation of all supernumerary embryos and tranfser in unstimulated cycles. In both study arms a blood sample on the day of ovulation trigger is mandatory to measure serum progesterone as a marker for endometrium receptivity.

Study burden and risks

No incapacitated subjects nor minors are involved in this study. No risks additional to standard treatment are associated with the study. Benefits of participating in the study are potential higher pregnancy chances in the freeze-all arm.

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

Women between 18 and 43 years of age who start their first IVF/ICSI.

Exclusion criteria

1. Women undergoing a PGD cycle.
2. Women undergoing IVF in a modified natural cycle.
3. Women undergoing IVF for oocyte donation
4. Women undergoing *rescue* IVF after overstimulation during IUI treatment.
5. 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: Will not start

Enrollment:	900
Type:	Anticipated

Ethics review

Approved WMO Date:	08-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2015
Application type:	Amendment
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

ID: 25760
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL53643.018.15
OMON	NL-OMON25760