A randomised controlled trial comparing in vitro maturation of oocytes with in vitro fertilisation in women with an increased risk of ovarian hyperstimulation syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24086

Source
NTR

Brief title
IVM-study

Health condition

Infertility, PCOS, OHSS

Sponsors and support

Primary sponsor: Jeroen Bosch Hospital
Source(s) of monetary or material Support: Jeroen Bosch Hospital

Intervention

Outcome measures

Primary outcome

Cumulative live birth rate after IVM/ICSI or COH/IVF/ICSI strategy including pregnancies from cryoembryos transferred within 12 months after the end of IVM/ICSI or COH/IVF/ICSI treatment.

Secondary outcome

1. Health and development of IVM/ICSI children versus COH/IVF/ICSI children in a 5 years' follow up program;

2. Number and nature of adverse events during or following the two treatment strategies, specifically including OHSS and multiple pregnancies;

3. Direct and indirect costs of the two treatment strategies;

4. Patients' quality of life scores as derived from validated questionnaires.

Study description

Background summary

Current artificial reproductive techniques (ART) as in vitro fertilisation (IVF) and intracytoplasmatic sperm injection (ICSI) require controlled ovarian hyperstimulation (COH) to increase the number of available mature oocytes. COH can lead to ovarian hyperstimulation syndrome (OHSS), a potentially life-threatening complication.

In in vitro maturation (IVM) immature oocytes are harvested from the ovaries without COH and matured in vitro in approximately 30 hours. Subsequently, these in vitro matured oocytes can be fertilised by IVF or ICSI. Due to the absence of COH, IVM has especially potential for patients with an increased risk of developing OHSS, such as polycystic ovary syndrome (PCOS)-patients. Further benefits of IVM extend to a reduction of treatment burden and reduced costs.

We propose a study to evaluate the effectiveness of IVM/ICSI.

In this multicenter randomised clinical trial we will compare two IVM/ICSI cycles versus one conventional IVF/ICSI cycle in a period of three months.

The trial will be preceded by a pilot study of 50 non-randomised IVM cycles. A total of 450 patients will be included. The primary endpoint will be ongoing pregancy rate. Secondary endpoints will be live birth rate, multiple pregnancy rate, clinical pregnancy rate, embryo quality, occurrence of adverse events as OHSS, patients' quality of life and costs per livebirth.

Study objective

A randomized controlled trial to compare the following strategies: two IVM-ICSI cycles or one COH-IVF/ICSI cycle. These strategies are expected to have comparable outcomes for ongoing pregnancy rates and direct costs (treatment costs). IVM is expected to have favourable outcomes for indirect costs (less complications) and quality of life scores.

Our hypothesis is the non-inferiority of the IVM-ICSI strategy to the COH-IVF or COH-ICSI strategy.

Study design

N/A

Intervention

2 IVM/ICSI cycles or 1 COH/IVF or COH/ICSI cycle.

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Eligibility criteria

Inclusion criteria

1. Women with PCOS according to the Rotterdam Criteria (The Rotterdam ESHRE/ASRM-Sponsored PCOS consensus workshop group, 2004) which not did achieve an ongoing pregnancy after ovulation induction (with clomiphene citrate or LEO and rFSH);

2. Women with an IVF or ICSI indication and increased risk for developing OHSS (history of OHSS or cycle cancellation for imminent OHSS).

Exclusion criteria

1. Woman or partner younger than 18 years and woman older than 38 years;

2. Unable to speak or read the Dutch language;

3. Medical contraindication for pregnancy or childbirth;

4. Positive serology for Hepatitis B, C or HIV;

5. Diminished ovarian reserve: early follicular serum FSH > 10 IU/l and/or poor response during earlier COH/IVF or COH/ICSI with ³ 150 IU rFSH/day;

6. Persisting ovarian cysts > 30 mm diameter.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	450
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-06-2010

Application type: First submission

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
NTR-new	NL2248
NTR-old	NTR2375
Other	ISRCTN : 61229302
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A