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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24086

Bron
NTR

Verkorte titel
IVM-study

Aandoening

Infertility, PCOS, OHSS

Ondersteuning

Primaire sponsor: Jeroen Bosch Hospital
Overige ondersteuning: Jeroen Bosch Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-06-2010

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2248
NTR-old	NTR2375
Ander register	ISRCTN : 61229302
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A