

Treatment of couples with unexplained subfertility and an unfavourable prognosis. A randomised trial comparing the effectiveness of IUI with ovarian hyperstimulation and IVF with single embryo transfer.

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One cycle of IVF-eSET followed by transfer of frozen embryos is at least as effective as three cycles of IUI-COH in terms of ongoing pregnancy. Multiple pregnancies however can largely be prevented by treating women with IVF-eSET.

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

Samenvatting

ID

NL-OMON21644

Bron

NTR

Verkorte titel

SETI-study (Single Embryo Transfer or IUI)

Aandoening

Unexplained subfertility or mild male subfertility

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ongoing pregnancy defined as registered heartbeat on ultrasound beyond 12 weeks of gestation.

Toelichting onderzoek

Achtergrond van het onderzoek

Couples with unexplained or mild male subfertility and a small chance of spontaneous pregnancy (<30%, calculated by the validated model of Hunault (Hunault et al., 2005, Van der Steeg et al., Submitted)), are currently treated with Intrauterine Insemination (IUI) and Controlled Ovarian Hyperstimulation (COH). This treatment results in 10-20% multiple pregnancies. Multiple pregnancies more often result in obstetrical and neonatal complications- e.g. premature birth, growth retardation and preeclampsia. These complicated pregnancies result in higher medical costs. Usually these subfertile patients are treated with IUI-COH followed by In Vitro Fertilization (IVF) with Double Embryo Transfer (DET). However an alternative strategy to prevent multiples would be IVF with Single Embryo Transfer (SET), and cryopreservation of spare embryos.

Our hypothesis is that one cycle of IVF-SET followed by embryo-transfers of cryo-preserved embryos is comparable to three cycles of IUI-COH concerning ongoing pregnancy and costs of these treatments. Multiple pregnancies however are largely prevented.

Our aim is to test our hypothesis in 100 subfertile couples which would in our setting normally have been treated with IUI-COH. The primary outcome measure in both groups is ongoing pregnancy. Secondary outcomes are multiple pregnancies, clinical pregnancies, life birth and complications during pregnancy.

Doel van het onderzoek

One cycle of IVF-eSET followed by transfer of frozen embryos is at least as effective as three cycles of IUI-COH in terms of ongoing pregnancy. Multiple pregnancies however can largely be prevented by treating women with IVF-eSET.

Onderzoeksproduct en/of interventie

Comparison of IVF in a long protocol with elective Single Embryo Transfer, and IUI-COH, in couples with unexplained or mild male subfertility and poor fertility prospects.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female age between 18 and 36 years;
2. Couples must be diagnosed with unexplained subfertility, defined as normal semen (pre-wash total motile sperm count of at least 40 million), spontaneous ovulatory cycle and patent Fallopian tubes, or with mild male subfertility, defined as a post-wash total motile sperm count above 3 million;
3. The couple has poor fertility prospects as calculated by the validated model of Hunault (Hunault et al., 2005, Van der Steeg et al., Submitted). A poor fertility prospect is defined as a chance of spontaneous pregnancy below 30% within 12 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Polycystic ovary syndrome;
2. Endocrinopathological disease like: Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, imminent ovarian failure, premature ovarian failure,

hypothalamic amenorrhea, hypothyroidy, diabetes mellitus type I;

3. If not willing or able to sign the consent form.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2006
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	23-11-2006
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	NL811
NTR-old	NTR824
Ander register	: N/A
ISRCTN	ISRCTN86744378

Resultaten

Samenvatting resultaten

N/A