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.

No registrations found.

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

Summary

ID

NL-OMON21644

Source
NTR

Brief title
SETI-study (Single Embryo Transfer or IUI)

Health condition

Unexplained subfertility or mild male subfertility

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Multiple pregnancy, defined as registered heartbeat of at least two foetuses at 12 weeks of gestation;
2. Clinical pregnancy, defined as any registered embryonic heartbeat at sonography;
3. Live birth, defined as the birth of at least one living child;
4. Pregnancy complications (preterm birth < 37 weeks, birth weight < 2.500 gram, Pregnancy Induced Hypertension (PIH), (pre-) eclampsia, HELLP).

Study description

Background summary

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.

Study objective

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.

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2006
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-11-2006
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	NL811
NTR-old	NTR824
Other	: N/A
ISRCTN	ISRCTN86744378

Study results

Summary results
N/A