Prevention of multiple pregnancies in couples with unexplained or mild male subfertility

No registrations found.

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

Summary

ID

NL-OMON20581

Source
Nationaal Trial Register

Brief title
INeS-study

Health condition

delivery, pregnancy_outcome, pregnancy_multiple, insemination_artificial, fertilization_in_vitro,
embryo_transfer, patient_preference

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Center For Reproductive Medicine
Source(s) of monetary or material Support: ZON-MW

Intervention

Outcome measures

Primary outcome

Birth of a healthy child.

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. Neonatal mortality;
4. Pregnancy complications (preterm birth < 37 weeks, birth weight < 2.500 gram, Pregnancy Induced Hypertension (PIH), (pre-) eclampsia, HELLP);
5. Costs.

Study description

Background summary

In couples with unexplained subfertility or mild male subfertility and an unfavourable prognosis for conception intra-uterine insemination with controlled ovarian hyperstimulation is standard treatment. The disadvantage of the adjuvant ovarian hyperstimulation is the risk of multiple pregnancies leading to maternal and neonatal complications. Single embryo transfer (SET) either in IVF cycles with mild ovarian hyperstimulation or in the manipulated natural cycle IVF are alternative treatments that prevent multiple pregnancies.

The aim of this study is to reduce multiple pregnancies while retaining acceptable delivery rates in couples with unexplained subfertility or mild male subfertility that have a low chance of a treatment independent pregnancy. We therefore compare six cycles of intra-uterine insemination with controlled ovarian hyperstimulation, six cycles of manipulated natural cycle IVF, and three cycles with IVF-eSET plus cryo-cycles within a time frame of 10 months.
All academic centers and their affiliated clinics in the Netherlands will participate in this multicenter trial. A total of 600 couples will be included.
We will compare the primary outcome of birth of a healthy child, multiple pregnancy, the costs, and women’s experience to the treatments in the three groups..
A cost-effectiveness analysis will be performed with costs of treatment until 6 weeks after the delivery of a child within a treatment time horizon of 10 months

Study objective

Multiple pregancies can be prevented without loss of pregnancy rates by treating couples with manipulated natural cycle IVF or with IVF-eSET plus cryo-cycles instead of standard treatment with intra-uterine insemination and controlled ovarian hyperstimulation.

Intervention

The comparisons are six cycles of intra-uterine insemination with controlled ovarian hyperstimulation, six cycles of manipulated natural cycle IVF, and three cycles with IVF-eSET plus cryo-cycles within a time frame of 10 months.

Contacts

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Eligibility criteria

Inclusion criteria

Couples are eligible if the following apply:
1. Female age between 18 and 38 years.
2. Failure to conceive within at least 12 months of unprotected intercourse.
3. The couple has poor fertility prospects as calculated by the validated model of Hunault (Hunault et al., 2005; Van der Steeg et al., 2006). A poor fertility prospect is defined as a chance of spontaneous pregnancy below 30% within 12 months.

Exclusion criteria

Couples must not be entered if any of the following apply:
1. Polycystic ovary syndrome or any other anovulation.
2. Post-wash total motile sperm count below 3 million.
3. Double-sided tubal pathology.
4. Endocrinopathological disease like: Cushing syndrome, adrenal hyperplasia, hyperprolactinemia, acromegaly, imminent ovarian failure, premature ovarian failure, hypothalamic amenorrhea, hypothyroidy, diabetes mellitus type I.
5. Negative post-coitus test.
6. 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:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-03-2007
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	NL915
NTR-old	NTR939
Other	:
ISRCTN	ISRCTN52843371

Study results

Summary results
http://www.bmj.com/content/350/bmj.g7771