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Treatment of couples with unexplained subfertility and an unfavourable prognosis: a randomised trial comparing the effectiveness of intrauterine insemination with ovarian hyperstimulation and in-vitro fertilisation with single embryo transfer

Submission date	Recruitment status	[ ] Prospectively registered
28/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/01/2021	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL811, NTR824

Study information

Scientific Title
Treatment of couples with unexplained subfertility and an unfavourable prognosis: a randomised trial comparing the effectiveness of intrauterine insemination with ovarian hyperstimulation and in-vitro fertilisation with single embryo transfer

Acronym
SETI-study (Single Embryo Transfer or IUI)

Study objectives
One cycle of In-Vitro Fertilisation-elective Single Embryo Transfer (IVF-eSET) followed by transfer of frozen embryos is at least as effective as three cycles of Intra-Uterine Insemination-Controlled Ovarian Hyperstimulation (IUI-COH) in terms of ongoing pregnancy. Multiple pregnancies however can largely be prevented by treating women with IVF-eSET.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the ethics board of the Academic Medical Centre Amsterdam on March 6th 2006 (reference number: MEC 294).

Study design
Randomised, controlled, parallel group multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unexplained Subfertility

Interventions
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.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

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

Key secondary outcome(s))
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 less than 37 weeks, birth weight less than 2.5 gram, Pregnancy Induced Hypertension (PIH), (pre-) eclampsia, Haemolysis, Elevated Liver, Low Platelet [HELLP])

Completion date
01/06/2008

Eligibility

Key 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 three million
3. The couple has poor fertility prospects as calculated by the validated model of Hunault. A poor fertility prospect is defined as a chance of spontaneous pregnancy below 30% within 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
116

Key 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

Date of first enrolment
01/06/2006

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Organon (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011	14/01/2021	Yes	No