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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 02/05/2007 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 02/05/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 15/01/2015 | 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

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

### Acronym
INeS-study

### Study objectives
Multiple pregnancies can be prevented without loss of pregnancy rates by treating couples with manipulated natural cycle In Vitro Fertilisation (IVF) or with IVF-eSET (Single Embryo Transfer) plus cryo-cycles instead of standard treatment with intra-uterine insemination and controlled ovarian hyperstimulation.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the local medical ethics committee

### Study design
Randomised, active controlled, parallel group, multicentre trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

### Participant information sheet

### Health condition(s) or problem(s) studied
Multiple pregnancies

### Interventions
The comparisons are:
1. Six cycles of intra-uterine insemination with controlled ovarian hyperstimulation
2. Six cycles of manipulated natural cycle IVF
3. Three cycles with IVF-eSET plus cryo-cycles

Performed within a time frame of 10 months

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Birth of a healthy child.

### Secondary outcome measures
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:
a. preterm birth less than 37 weeks
b. birth weight less than 2.500 grams
c. Pregnancy Induced Hypertension (PIH)
d. (pre)-eclampsia, HELLP (Haemolysis, Elevated Liver enzymes, Low blood levels of Platelets)
5. Costs

### Overall study start date
01/07/2007

### Completion date
12/12/2010

## Eligibility

### Key inclusion criteria
Couples are eligible if the following apply:
1. Females aged 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. A poor fertility prospect is defined as a chance of spontaneous pregnancy below 30% within 12 months

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
38 Years

### Sex
Female

### Target number of participants

600

### Key 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:
a. Cushing syndrome
b. adrenal hyperplasia
c. hyperprolactinaemia
d. acromegaly
e. imminent ovarian failure
f. premature ovarian failure
g. hypothalamic amenorrhoea
h. hypothyroidy
i. diabetes mellitus type one
5. Negative post-coitus test
6. If not willing or able to sign the consent form

### Date of first enrolment
01/07/2007

### Date of final enrolment
12/12/2010

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Academic Medical Centre**
Amsterdam
Netherlands
1100 DE

## Sponsor information

### Organisation
Academic Medical Centre (AMC) (The Netherlands)

### Sponsor details
Center For Reproductive Medicine
P.O. Box 22660

Amsterdam
Netherlands
1100 DD

### Sponsor type
Hospital/treatment centre

### Website
http://www.amc.uva.nl/index.cfm?sid=1

### ROR
https://ror.org/03t4gr691

## Funder(s)

### Funder type
Research organisation

### Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 | 09/01/2015 | | Yes | No |