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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