

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

Submission date 02/05/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 02/05/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/01/2015	Condition category Pregnancy and Childbirth	☐ Individual participant data

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
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

Study type(s)

Prevention

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(s)

Birth of a healthy child.

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. 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

38 years

Sex

Female

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)

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

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