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Effectiveness of intrauterine insemination with ovarian hyperstimulation in couples with an unexplained moderately reduced fertility

Submission date 20/12/2005	**Recruitment status** No longer recruiting
Registration date 20/12/2005	**Overall study status** Completed
Last Edited 19/10/2007	**Condition category** Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

Study objectives
There is no additional benefit of Intrauterine Insemination (IUI) with Controlled Ovarian Hyperstimulation (COH) over expectant management for 6 months in couples with unexplained subfertility and a chance of a spontaneous pregnancy between 30% and 40%. Categorisation of unexplained subfertile couples by their prognosis can identify those couples who benefit from IUI with COH and those who do not.

Ethics approval required
Old ethics approval format

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

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
After informed consent had been given, couples were randomly allocated between IUI with COH and expectant management for six months.

Couples allocated to IUI with COH started treatment in the next cycle. Controlled ovarian hyper stimulation as well as semen preparation and insemination regimens were performed according to hospital-specific protocols.

Couples allocated to expectant management were followed until an ongoing pregnancy occurred within six months, these pregnancies were finally followed until birth. If no pregnancy occurred, follow-up ended after this period. If a pregnancy miscarried, follow-up continued until the next pregnancy or the end of the six months period.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary endpoint was ongoing pregnancy within six months. Ongoing pregnancy was defined as the presence of foetal cardiac activity at transvaginal sonography at a gestational age of at least 12 weeks.

Secondary outcome measures
Secondary endpoints were total number of clinical pregnancies, miscarriages and multiple pregnancies.

Overall study start date
01/06/2002

Completion date
01/07/2005

Eligibility

Key inclusion criteria
All subfertile couples in whom no reason is found during the basic fertility work-up for their subfertility and in whom their spontaneous pregnancy chance in the next year, calculated by the results of the basic fertility work-up, is between 30% and 40%.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
250

Key exclusion criteria
All couples in whom a reason is found for their subfertility or who are having another prognosis calculated

Date of first enrolment
01/06/2002

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

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	15/07/2006		Yes	No