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Follicle diameter study: timing of human chorionic gonadotropin administration according to predetermined criteria of follicular size

Submission date
08/02/2007

Recruitment status
No longer recruiting

Registration date
08/02/2007

Overall study status
Completed

Last Edited
15/08/2011

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

Study website
http://www.studies-obsgyn.nl

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

Study objectives
To assess whether delayed administration of human Chorionic Gonadotropin (hCG) for controlled ovarian hyperstimulation for In Vitro Fertilisation (IVF) and embryo transfer leads to an increased advanced stage of endometrium, and prolonged exposure to high levels of estradiol which may result in a lower pregnancy rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Ethics Board of the Academical Medical Center, Amsterdam, on the 20th July 2005 (ref: MEC 05/161 #05.17.1237).

Study design
Randomised, active-controlled, parallel group, multicentre 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
In Vitro Fertilisation (IVF), timing of human Chorionic Gonadotropin (hCG) administration, follicle size

Interventions
hCG administration for follicular maturation when the dominant follicle measures 18 mm compared to hCG administration for follicular maturation when the dominant follicle measures 22 mm.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Human Chorionic Gonadotropin (hCG)

Primary outcome measure
Ongoing pregnancy rate, defined as a positive foetal heartbeat by ultrasound at ten weeks after oocyte retrieval.

Secondary outcome measures
1. Endometrium thickness, three-layer aspect
2. Total days of controlled hyper stimulation
3. Total amount of recombinant FSH (rFSH) used
4. Total number of retrieved oocytes
5. Number of score one oocytes (IVF only)
6. Number of metaphase two oocytes (ICSI only)
7. Fertilisation rate
8. Number and quality of embryos
9. Pronuclear morphology
10. Presence of early cleavage
11. Daily morphological quality of embryos until transfer
12. Number of embryos suited for cryo-preservation
13. Ovarian Hyper-Stimulation Syndrome (OHSS)/discontinuation due a high risk of OHSS
14. Biochemical and clinical pregnancy rates, defined as a increase in serum hCG or a positive pregnancy test and positive heartbeat by ultrasound at seven weeks after oocyte retrieval, respectively

Overall study start date
01/04/2006

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Age between 18 and 42 and 11 months
2. Valid indication for IVF or Intra-Cytoplasmic Sperm Injection (ICSI)
3. Undergoing their first or second IVF/ICSI attempt
4. Normal Follicle-Stimulating Hormone (FSH) levels (less than 15)
5. Antral follicle count more than five for women between 40 and 43

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
1. Endocrinopathological disease as: Poly-Cystic Ovarian Syndrome (PCOS), cushing syndrome, adrenal hyperplasia, hyperprolactinaemia, acromegaly, hypothalamic amenorrhoea, hypothyroidy, diabetes mellitus type one
2. Premature ovarian failure defined as a FSH level on cycle-day three of more than or equal to 15 IU at the age of 40
3. Low responders defined as follicle growth of less than three follicles during controlled ovarian hyperstimulation (including the dominant follicle)

Date of first enrolment
01/04/2006

Date of final enrolment
01/04/2008

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

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Organon (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	01/05/2011		Yes	No