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In Vitro Maturation as part of the treatment of infertility in women with PolyCystic Ovaries. Is priming with hCG favourable? A prospective randomized study

Submission date
27/03/2007

Recruitment status
No longer recruiting

Registration date
15/05/2007

Overall study status
Completed

Last Edited
10/10/2014

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
OUHIVMproj-1-pco-hcg

Study information

Scientific Title

Acronym
IVM-PCO-project-OUH

Study objectives
Antral ovarial follicles are possibly sensitive for priming with hCG, due to expression of LH-receptors in granulosa cells. The in vitro maturation process might benefit from priming with hCG before aspiration of small follicles (<11 mm). The size of the follicles, measured by ultrasound scanning, and serum concentration of various hormones, will be related to the outcome of the treatment in each group (hCG vs no hCG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The scientific ethical commitee for the counties of Funen and Vejle, 11/04/2006, ref: VF 20050163

Study design
Prospective open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Infertility and PCO.

Interventions
hCG-injection vs no injection 36 hours before aspiration of oocytes.

Randomization is performed by a nurse two days before aspiration of immature oocytes. Block randomization is used, at a size of 50 (25+25) patients.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcome measures amended as of 26/06/2007:
1. Maturation rate (number of mature [M2] oocytes per number of aspirated oocytes) at 30 and 46 hours
2. Fertilization rate (number of fertilized oocytes per number of matured oocytes) at 46 and 70 hours

Primary outcome measures provided at time of registration:
1. Maturation rate (number of mature [M2] oocytes per number of aspirated oocytes)
2. Fertilization rate (number of fertilized oocytes per number of matured oocytes)

Secondary outcome measures
Secondary outcome measures amended as of 26/06/2007:
1. Number of transferable embryos with normal development on day 2 after fertilization, as a fraction of aspirated, matured and fertilized oocytes in IVF and Intra Cytoplasmatic Sperm Injection (ICSI) groups
2. Maturation rate in relation to follicle size (46 hours after maturation)
3. Maturation rate in relation to serum concentrations of various hormones, measured on various cycle days and days of randomization and aspiration

Secondary outcome measures provided at time of registration:
1. Number of transferable embryos with normal development on day 2 after fertilization, as a fraction of aspirated, matured and fertilized oocytes in IVF and Intra Cytoplasmatic Sperm Injection (ICSI) groups
2. Maturation rate in relation to follicle size
3. Maturation rate in relation to serum concentrations of various hormones, measured on various cycle days and days of randomization and aspiration

Overall study start date
01/04/2006

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Women with PolyCystic Ovaries (PCO) according to Rotterdam criteria (2003)
2. Referred to the Fertility Clinic, Odense University Hospital
3. Candidates for IVF-treatment according to the standards of the Fertility Clinic

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Normal ovarial morphology
2. Manifest diseases requiring medication e.g. diabetes mellitus
3. Endocrine diseases, e.g. hyperprolactinaemia, hyper-and hypothyroidism
4. Abuse of drugs or alcohol
5. More than two previous IVF treatments

Date of first enrolment
01/04/2006

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Denmark

Study participating centre
Fertility Clinic
Odense C
Denmark
5000

Sponsor information

Organisation
Odense University Hospital (Denmark)

Sponsor details
c/o Prof Lars G Westergaard
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ey0ed83

Funder(s)

Funder type
Not defined

Funder Name
Fertility Clinic, Department of Obstetrics and Gynaecology , Odense University Hospital (Denmark)

Funder Name
University of Southern Denmark (Denmark)

Funder Name
MediCult (manufacturer of laboratory IVM-medium) (Denmark)

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