

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	<input type="checkbox"/> Prospectively registered
Registration date 15/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/10/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 ovarian 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 committee 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 Cytoplasmic 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 Cytoplasmic 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 ovarian 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

Fertility Clinic

Department of Obstetrics and Gynaecology

Odense University Hospital

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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