# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
27/03/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/05/2007	Completed	Results
Last Edited	Condition category	Individual participant data
10/10/2014	Pregnancy and Childbirth	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

## Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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)

## Key secondary outcome(s))

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

## 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

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

Female

## 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)

## **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**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration