

# In vitro maturation of human oocytes with subsequent IVF or ICSI . An observational study with follow up of the children.

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The objective of this observational study is the safe introduction of clinical applied IVM in The Netherlands. During this study, the number and quality of the oocytes and embryos will be studied as well as pregnancy development. Emphasis will be on...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Endocrine disorders of gonadal function
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON31686

### Source

ToetsingOnline

### Brief title

In vitro maturation

### Condition

- Endocrine disorders of gonadal function
- Sexual function and fertility disorders
- Obstetric and gynaecological therapeutic procedures

### Synonym

polycystic ovarian syndrome, reduced fertility

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Sint Elisabeth Ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ICSI, IVF, IVM, PCOS

## Outcome measures

### Primary outcome

- \* Nr, development and quality of embryos on day 3.

### Secondary outcome

IVM treatment:

- \* Nr of oocytes on day 0, after ovum pick-up.
- \* Nr in vitro matured (MII) oocytes on day 1 (only visible with ICSI).
- \* Nr of fertilised oocytes, pronuclei score.
- \* Nr, development and quality of transferred embryos and cryopreserved embryos.

pregnancy:

- \* Result pregnancytest about 2 weeks after ovum pick-up.
- \* Heartbeat by ultrasound, 6-8 weeks after ovum pick-up.
- \* Follow up pregnancy

partus:

- \* Amenorrhoe
- \* partus (spontaneous, sectio, forceps, vacuum)
- \* Complications

children:

- \* Standard screening directly after birth according to the Landelijke

Verloskundige Registratie (LVR)

- \* Follow up of children will be performed on several domains according to national and international standards. Shortly after birth, at 6 months, 1-, 2- and 5-years of age mental and motoric development will be scored according to national and international standards.

## Study description

### Background summary

In the menstrual cycle a cohort of early antral follicles is present at the onset of the follicular phase. A few of these early antral follicles are recruited for further growth and development. However only one will become the dominant follicle, resulting in atresia of the others.

During IVF-treatment women are stimulated by subcutaneous injections with supraphysiological doses of FSH, often combined with downregulation of the spontaneous natural cycle with GnRH analogue (COH, controlled ovarian hyperstimulation). This overrules the natural dominance selection and leads to support of the complete recruited cohort, resulting in ideally 8-15 follicles. The oocytes are then picked up from these follicles by transvaginal ovum pick-up and most oocytes are in the metaphase II stage. Subsequently IVF or ICSI can be performed.

Disadvantages of COH are the physical impact on the patient as well as the risk of ovarian hyperstimulation syndrome (OHSS). In severe cases (0,5-5% of all IVF cycles) this forms a potential life-threatening complication. Especially patients diagnosed with polycystic ovarian syndrome (PCOS) have an increased risk for developing OHSS (Delvigne and Rozenberg, 2002).

An alternative for conventional IVF with COH is in vitro maturation (IVM). In this approach none or only minimal stimulation with FSH is applied. Ovum pick-up takes place in the early antral phase and only immature (metaphase I) oocytes are harvested. These oocytes are transferred to IVM culture medium and mature in vitro to the metaphase II stage within 24-36 hours. Subsequently these matured oocytes are used for IVF or ICSI in the same way as in conventional IVF with COH.

The main advantage of IVM is the absence of COH and therefore the risk for OHSS is abolished. Furthermore this procedure is especially useful for PCOS patients

as they have more early antral oocytes present due to their PCOS.

## **Study objective**

The objective of this observational study is the safe introduction of clinical applied IVM in The Netherlands. During this study, the number and quality of the oocytes and embryos will be studied as well as pregnancy development. Emphasis will be on the long term development of the children born after this IVM procedure. Shortly after birth, at 6 months, 1-, 2- and 5-years of age mental and motoric development will be scored according to national and international standards.

## **Study design**

This is an observational study with the following design.

Patients will be informed extensively before they will participate in this study. Participation will only take place after written informed consent by the patients.

The menstrual cycle of the patient will be monitored endocrinologically as well as by ultrasound. The appearance of a dominant follicle in combination with an increase of the endometrium thickness to 5 mm determines an appointment for ovum pick-up the following day. Ovum pick-up will be performed transvaginal under ultrasound guidance and local anaesthesia with lidocain or intravenous fentanyl as is routinely used in our clinic. The oocytes are collected by a laboratory technician using an (veterinary) Embryo Collector (steel mesh) and transferred to IVM culture medium. Culture for 30 hours in this medium leads to final oocyte maturation and the matured oocytes are used for IVF or ICSI.

## **Study burden and risks**

The main advantage of IVM is the absence of COH and therefore the risk for OHSS is abolished.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

PCOS or patients with a previous occurrence of OHSS (ovarian hyperstimulation syndrome)

### Exclusion criteria

older than 38 years of age, early-follicular serum FSH over 10 IU/ml

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

## Recruitment

NL

Recruitment status: Will not start

Enrollment: 400

Type: Anticipated

## Ethics review

Not approved

Date: 28-10-2008

Application type: First submission

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

### Register

CCMO

### ID

NL21244.000.08