

# A controlled trial of ovulation stimulation with intrauterine insemination (IUI) versus in vitro fertilisation (IVF)

<b>Submission date</b> 11/02/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/09/2014	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

### Study objectives

Added 16/12/2008:

A controlled trial of ovulation stimulation with intrauterine insemination versus in vitro fertilisation on clinical pregnancy rates in patient with idiopathic or mild male infertility.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Royal Women's Hospital Research and Ethics Committee, ref: 03/27

### Study design

Randomised 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

Idiopathic or mild male infertility

### Interventions

Standard IVF, or low dose follicle stimulating hormone (FSH) with IVF or IUI

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

Added 16/12/2008:

Clinical pregnancy (ultrasound foetal heart[s]).

## Secondary outcome measures

Added 16/12/2008:

Economic analysis: relative cost per live birth pregnancy.

## Overall study start date

01/07/2004

## Completion date

31/12/2005

# Eligibility

## Key inclusion criteria

1. Infertility of 12 months or longer duration
2. Primary or secondary infertility
3. New patient or patient returning after an interval of longer than 1 year
4. Female age 18-42, male age 18-60 years
5. Detailed male and female partner clinical evaluation, investigation of semen quality and objective evidence of ovulation and tubal patency

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

60 Years

## Sex

Female

## Target number of participants

600

## Key exclusion criteria

1. Coital disorders, including infrequent or mistimed coitus (<1 per 3 days during mid cycle)
2. Tubal obstruction (one or both on sonohysterogram, laparoscopy or laparotomy) or known ligation
3. Male infertility requiring intracytoplasmic sperm injection (ICSI): average sperm concentration less than 2 million/ml, progressive motility less than 25%, or abnormal morphology greater than 95% in two or more semen tests performed within the previous 12 months in the Royal Women's Hospital andrology laboratory, sperm autoimmunity (Immunobead Test [IBT] IgG or IgA antibodies on >50% of motile sperm together with blocked sperm mucus penetration: < 3 cm at 1h in the capillary tube test), reduced sperm zona pellucida (ZP) binding (ratio <0.3) or disordered ZP-induced acrosome reaction (ZPIAR) (<16%) confirmed in 2 sperm ZP interaction tests, or less than 2 million motile sperm for IUI assessed by trial sperm preparation

4. Untreated ovulatory disorders (patients treated for 6 ovulatory cycles without a pregnancy can enter the trial)
5. Ovarian endometrioma (patients with treated or untreated mild endometriosis can enter the trial)
6. Miscellaneous (for example: a contraindication to multiple pregnancy)
7. Currently treated patients

**Date of first enrolment**

01/07/2004

**Date of final enrolment**

31/12/2005

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

University of Melbourne Department of Obstetrics and Gynaecology

Carlton, Victoria

Australia

3053

## **Sponsor information**

**Organisation**

The Royal Women's Hospital (Australia)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03grnna41>

# Funder(s)

## Funder type

Industry

## Funder Name

Added 16/12/2008:

## Funder Name

Serono Australia Ltd (Australia)

## Funder Name

Melbourne IVF (Australia)

# 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?
<a href="#">Results article</a>	results	01/04/2014		Yes	No