

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

Submission date 11/02/2004	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 17/03/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/09/2014	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
03/07; ACTRN12605000027617

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

Study type(s)

Treatment

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(s)

Added 16/12/2008:

Clinical pregnancy (ultrasound foetal heart[s]).

Key secondary outcome(s))

Added 16/12/2008:

Economic analysis: relative cost per live birth pregnancy.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

60 years

Sex

Female

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)

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

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?
Results article	results	01/04/2014		Yes	No