ISRCTN28780587 https://doi.org/10.1186/ISRCTN28780587

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

Registration date
17/03/2004

Overall study status
Completed

Last Edited
19/09/2014

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gordon Baker

Contact details
University of Melbourne Department of Obstetrics and Gynaecology
Royal Women's Hospital
132 Grattan Street
Carlton, Victoria
Australia
3053
+61 (0)3 93442130
g.baker@unimelb.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 ferilisation 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
132 Grattan Street
Carlton, Victoria
Australia
3053
+61 (0)3 9233 2759
arhtur.hui@rwh.org.au

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?
Results article	results	01/04/2014		Yes	No