ISRCTN82461750 https://doi.org/10.1186/ISRCTN82461750

A trial comparing two commonly used doses of fertility drugs (gonadotrophins) in women likely to have normal response during in vitro fertilisation (IVF)

Submission date
19/09/2008

Recruitment status
No longer recruiting

Registration date
20/11/2008

Overall study status
Completed

Last Edited
05/04/2012

Condition category
Urological and Genital Diseases

[_] 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

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Additional identifiers

Protocol serial number
IVFAFC1

Study information

Scientific Title
A randomised controlled trial of 225 versus 300 IU recombinant follicle stimulating hormone (FSH) for ovarian stimulation in predicted normal responders by antral follicle count

Study objectives
To test the hypothesis that, among women predicted to have a normal ovarian response, ovarian stimulation using 300 IU follicle stimulating hormone (FSH) results in retrieval of more mature oocytes than 225 IU.

As of 05/04/2012, the anticipated end date of trial has been updated from 01/10/2008 to 01/04/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Obtained from National Health Service (NHS) research ethics committee on the 14th September 2008 (ref: 06/MRE04/33).

Study design
A prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infertility

Interventions
Conventional controlled ovarian stimulation using a fixed daily doses of 225 IU or 300 IU of recombinant FSH. The total duration of treatment is 6 weeks with 2 weeks of the research medication and up to 8 weeks of follow up.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Follicle stimulating hormone (FSH)

Primary outcome(s)
Number of mature oocytes retrieved, measured at about 2 - 3 weeks of starting the research medication.

Key secondary outcome(s))
1. Number of follicles measuring more than 10 mm and more than 14 mm in diameter on the day of human chorionic gonadotropin (hCG) administration
2. Cycle cancellation due to poor ovarian response
3. The number of frozen embryos
4. The prevalence of moderate or severe ovarian hyperstimulation syndrome (OHSS)
5. The clinical and on-going pregnancy rates

Measured at 10 weeks at the latest.

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Female subjects aged between 20 and 38 years, undergoing first, second or third cycle of in vitro fertilisation (IVF)/intra-cytoplasmic sperm injection (ICSI) treatment
2. Subjects must have a regular spontaneous menstrual cycle of 21 to 35 days
3. A basal FSH level of less than or equal to 12 IU
4. Presence of both ovaries
5. Total antral follicle count of between 7 and 22. Subjects who have not had any ovarian surgery in the past.
6. Subjects, who have a body mass index (BMI) of 20 to 35 kg/m^2
7. Subjects must have signed and dated the informed consent document indicating that the subject has been informed all the pertinent aspect of the trial
8. Subjects must be willing and comply with scheduled visits, treatment plan and laboratory tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Subjects who have an ovarian cyst (greater than 20 mm) or other significant pelvic pathology (uterine anomalies, uterine fibroids, endometrioma) at screening
2. Subjects who have an antral follicle count greater than or equal to 12 with in an ovary and/or an ovary volume of greater than 10 cm^3 on 3D ultrasound
3. Subjects whose infertility is caused by recognised endocrine abnormalities such as polycystic ovarian syndrome, hyperprolactinaemia and abnormal thyroid function
4. Subjects with any contraindications to IVF/ICSI treatment
5. Subjects who are taking concurrent corticosteroids or metformin

Date of first enrolment
01/10/2006

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Senior Lecturer, Consultant Obstetrician
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)
The University of Nottingham

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2010		Yes	No