

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	<input type="checkbox"/> Prospectively registered
Registration date 20/11/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/04/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Number of mature oocytes retrieved, measured at about 2 - 3 weeks of starting the research medication.

Secondary outcome measures

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.

Overall study start date

01/10/2006

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/m²
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

Age group

Adult

Sex

Both

Target number of participants

128

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 cm³ 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

England

United Kingdom

Study participating centre

Senior Lecturer, Consultant Obstetrician

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

c/o Paul Cartledge
Research Support and Commercialisation Office
University of Nottingham, University Park
Queens Medical Centre
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)**Funder type**

University/education

Funder Name

University of Nottingham (UK)

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

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	01/06/2010		Yes	No