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A randomised controlled trial comparing the Gonadotrophin Releasing Hormone agonist long regimen versus the Gonadotrophin Releasing Hormone agonist short regimen versus the Gonadotrophin Releasing Hormone antagonist regimen in poor responders undergoing in vitro fertilisation treatment

Submission date
01/09/2006

Recruitment status
No longer recruiting

Registration date
27/10/2006

Overall study status
Completed

Last Edited
05/11/2013

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

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Additional identifiers

EudraCT/CTIS number
2006-004460-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EudraCT No 2006-004460-31

Study information

Scientific Title

Acronym
PRINT (Poor Responders INtervention Trial)

Study objectives
Different interventions have been proposed to improve response to ovarian stimulation in poor responders. These include various interventions for downregulation, ovarian stimulation and adjuvant therapies. Following review and analysis of existing evidence for downregulation regimens we were not able to ascertain which the best down regulation regimen is for poor responders in In Vitro Fertilisation (IVF) treatment. We, therefore, propose a randomised trial to answer this question.

There is however lack of evidence to show that any one intervention improves outcome significantly. The purpose of this study is to compare the three most commonly used regimens in IVF treatment and find out whether any one regimen is significantly better.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 27/10/2006.

Study design
Prospective, concealed, single-blind, three-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Poor ovarian response in In Vitro Fertilisation (IVF)

Interventions
Each intervention group will be receiving one of the following treatments:
1. The Gonadotrophin Releasing Hormone (GnRH) agonist long regimen
2. The GnRH agonist short regimen
3. The GnRH antagonist regimen

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gonadotrophin Releasing Hormone (GnRH) agonist long regimen, GnRH agonist short regimen and GnRH antagonist regimen.

Primary outcome measure
Number of oocytes retrieved at egg collection

Secondary outcome measures
1. Total FSH dose used for ovarian stimulation
2. Number of mature oocytes retrieved
3. Number of embryos available for transfer
4. Clinical pregnancies (ultrasound evidence of foetal heart at eight weeks gestation)

Overall study start date
01/11/2006

Completion date
01/05/2008

Eligibility

Key inclusion criteria
Any woman undergoing an IVF treatment cycle with or without Intra Cytoplasmic Sperm Injection (ICSI) who is considered to be a "poor responder" is eligible to participate in the trial.

For this study a "poor responder" is defined as a woman who had a previous IVF treatment cycle in which she was stimulated with a daily dose of Follicle Stimulating Hormone (FSH) of 300 IU or more for at least nine days and:

1. Produced an inadequate number of mature follicles (three or less follicles measuring more than or equal to 17 mm, or
2. Had three or less oocytes retrieved at oocyte retrieval

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
34 participants in each arm giving a total of 102 participants

Key exclusion criteria
1. Women aged more than 40 years
2. Women with a single ovary

Date of first enrolment
01/11/2006

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Assisted Conception Unit
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust and King' s College London (UK)

Sponsor details

Guy's Hospital
St Thomas' Street
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/home.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Assisted Conception Unit, Guy's and St Thomas' NHS Foundation Trust (UK)

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	28/12/2007		Yes	No