

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 27/10/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/11/2013	Condition category Pregnancy and Childbirth	<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

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-004460-31

Protocol serial number

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

Study type(s)

Treatment

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(s)

Number of oocytes retrieved at egg collection

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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)

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

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