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A prospective randomised study of the optimal time for the administration of human chorionic gonadotropin (HCG) in women undergoing IVF in a gonadotropin releasing hormone (GnRH) antagonist cycle

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
03/08/2012

Condition category
Pregnancy and Childbirth

[_] 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436118096

Study information

Scientific Title

Study objectives
A prospective, randomised study on patients undergoing IVF or IVF/intracytoplasmic sperm injection (ICSI) receiving HCG injection in three different time scales (at the standard time, delay 24 or 48 h) when they are ready to be scheduled for the oocyte retrieval. HCG is employed to initiate maturation of oocytes and ovulation before the egg collection 36 h later. The main objective is to determine whether there is an optimal time to give HCG injection; and also to observe any differences in the number of eggs being collected, fertilisation rates, embryos quality and pregnancy rates among the three groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: In vitro fertilisation (IVF)

Interventions
Laboratory study; Case-note review; Randomised controlled trial, Random allocation to receive HCG injection at:

1. Standard time delay
2. 24 h delay
3. 48 h delay

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The main objective is to determine whether there is an optimal time to give HCG injection, and also to observe any differences in the number of eggs being collected, fertilisation rates, embryos quality and pregnancy rates among the three groups.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/07/2002

Completion date
31/01/2004

Eligibility

Key inclusion criteria
1. Patients undergoing their first or second cycle of IVF or IVF/intracytoplasmic sperm injection (ICSI).
2. Age of partner 19-36 years.
3. Body mass index 20-30 kg/m2.
4. Serum follicle-stimulating hormone (FSH) concentration in normal range.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
31/07/2002

Date of final enrolment
31/01/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Obstetrics & Gynaecology
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS 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	01/09/2012		Yes	No