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The use of metformin in in vitro fertilisation (IVF) treatment of patients with polycystic ovary syndrome (PCOS)

Submission date 12/09/2003	**Recruitment status** No longer recruiting
Registration date 12/09/2003	**Overall study status** Completed
Last Edited 29/04/2010	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436118094

Study information

Scientific Title

Study objectives
A prospective, randomised, double-blinded, placebo-controlled study using a short course of metformin treatment in patients with polycystic ovary syndrome or polycystic ovaries undergoing standard IVF treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised double-blinded placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Polycystic ovarian syndrome (PCOS)

Interventions
Laboratory study; Case-note review; Database analysis; Randomised controlled trial, Random allocation to:
A. Metformin alone
B. Metformin + low dose follicle-stimulating hormone (FSH)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in average oocyte retrieval rate, oocyte maturity, fertilisation rates, embryo cleavage rates, embryo quality and pregnancy rates. Change in ovarian hyperstimulation syndrome (OHSS) rates.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2001

Completion date
01/04/2005

Eligibility

Key inclusion criteria
Our unit performs about 1500 IVF cycles per year and 70% of the patients have only one cycle of treatment per year. Fifteen per cent of these patients have anovulatory infertility and almost 80% of this group of women will have PCOS. Therefore, about 125 subjects will be suitable for the trial. Assuming 75% of the subjects will participate in the trial, we should be able to recruit 100 patients per year.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2001

Date of final enrolment
01/04/2005

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
Government

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	01/06/2006		Yes	No