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

Submission date	Recruitment status	Prospectively registered		
12/09/2003	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2003	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
29/04/2010	Urological and Genital Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre Obstetrics & Gynaecology

Leeds United Kingdom LS1 3EX

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS 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	01/06/2006		Yes	No