

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/04/2010	<b>Condition category</b> Urological and Genital Diseases	<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

**Contact name**  
Mr AH Balen

**Contact details**  
Obstetrics & Gynaecology  
C Floor  
Clarendon Wing  
Leeds General Infirmary  
Leeds  
United Kingdom  
LS1 3EX  
+44 (0)113 392 2728  
adam.balen@leedsth.nhs.uk

## 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?
<a href="#">Results article</a>	results	01/06/2006		Yes	No