

The use of metformin in patients with polycystic ovarian syndrome requiring treatment with in vitro fertilisation (IVF)

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2015	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0024120995

Study information

Scientific Title

The use of metformin in patients with polycystic ovarian syndrome requiring treatment with in vitro fertilisation (IVF)

Study objectives

Metformin has been shown to be useful in patients with polycystic ovarian syndrome (PCOS) undergoing IVF. The aim of this study is to investigate whether metformin therapy in patients with polycystic ovaries can improve the fertilisation rates and significantly improve pregnancy rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Polycystic ovarian syndrome (PCOS)

Interventions

Group A will be given 500 mg metformin TDS for 1 month prior to their treatment. Group B will not be treated with metformin. Both groups will undergo standard IVF treatment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Metformin

Primary outcome(s)

1. Total number of follicles reaching 18 mm
2. Number of eggs obtained, number and quality of mature eggs, fertilisation rates
3. Total number of embryos, number and quality of embryos replaced and number of embryos frozen
4. Biochemical pregnancies, clinical pregnancies
5. Number of cycles abandoned for poor response and over response
6. Number of cases of ovarian hyperstimulation in each group

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

Patients with PCOS

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Homerton University Hospital NHS Trust

London

United Kingdom

E9 6SR

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Homerton University Hospital NHS Trust

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration