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

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/09/2015	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Richard Howell

Contact details
Fertility Unit
Homerton University Hospital NHS Trust
Homerton Row
London
United Kingdom
E9 6SR
+44 (0)20 8510 7660
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
1. Total number of folicles 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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Patients with PCOS

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

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
England

United Kingdom

Study participating centre
Homerton University Hospital NHS Trust
London
United Kingdom
E9 6SR

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
Homerton University Hospital NHS Trust

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