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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 summaryNot provided at time of registration