

Management of anovulation associated with polycystic ovarian syndrome: a randomised trial of clomid versus clomid plus metformin.

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 19/02/2014	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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
N0112128478

Study information

Scientific Title

Study objectives

Clomid plus metamorformin is a better treatment option than Clomid alone for subfertility associated with polycystic ovarian syndrome.

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)

Not Specified

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: PolyCystic Ovarian Syndrome (PCOS)

Interventions

Women will be randomised in blocks of six into two groups. One group will receive Clomid plus Metformin and the second group will receive Clomid alone.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

clomid versus clomid plus metformin

Primary outcome(s)

Pregnancy.

Key secondary outcome(s)

1. Ovulation
2. Level of luteinising hormone
3. Level of testosterone
4. Body Mass Index.

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

Subfertile women attending St Helier hospital fertility clinic with problem of anovulation associated with polycystic ovarian syndrome.

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

01/11/2003

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Epsom and St. Helier NHS Trust

Carshalton

United Kingdom

SM5 1AA

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration