

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/02/2014	Condition category Nutritional, Metabolic, Endocrine	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Pregnancy.

Secondary outcome measures

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

Overall study start date

01/11/2003

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

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre
Epsom and St. Helier NHS Trust
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University 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