ISRCTN77388772 https://doi.org/10.1186/ISRCTN77388772

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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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