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

Plain English Summary
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 hypothesis
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

Condition
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

Overall study end date
31/12/2007

Eligibility

Participant 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

Participant exclusion criteria
Not provided at time of registration

Recruitment start date
01/11/2003

Recruitment end date
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