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The effects of medical therapy on insulin resistance and the cardiovascular system in PolyCystic Ovarian Syndrome

Submission date	Recruitment status
28/03/2006	No longer recruiting
Registration date	**Overall study status**
03/04/2006	Completed
Last Edited	**Condition category**
11/04/2008	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.jeanhailes.org.au

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
PCOS

Study objectives
Women with polycystic ovarian syndrome (PCOS) and insulin resistance will have equivalent efficacy with metformin and both high- and low-dose oral contraceptives, yet the metabolic effects of the therapy will differ with metformin and the lower dose oral contraceptive pill (OCP) having relatively more favorable effects on insulin resistance and metabolic and cardiovascular parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Southern Health Human Ethics Committee in October 2002.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Polycystic ovarian syndrome

Interventions

Patients are randomised to receive one of the following interventions:
1. Control group: higher dose OCP - 35 mcg ethinyl oestradiol (EE), 2 mg cyproterone acetate
2. Metformin - 1 g greater than twice daily (bd)
3. Low dose OCP - 20 mcg EE, 100 mcg levonorgestrel and 50 mg aldactone bd

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ethinyl oestradiol (EE), cyproterone acetate, metformin, levonorgestrel and aldactone

Primary outcome measure
Effects on insulin resistance

Secondary outcome measures
1. Clinical symptom improvement
2. Arterial function

Overall study start date
01/10/2002

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Overweight women (body mass index [BMI] greater than 27 kg/m^2)
2. Aged 18 - 40 years with PCOS diagnosed from a history of perimenarchal onset of irregular cycles (less than 21 days or greater than 35 days) plus clinical manifestations of hyperandrogenism (hirsutism, acne) or biochemical hyperandrogenism with elevation of at least one circulating ovarian androgen (1990 National Institute of Health [NIH] criteria)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

Key exclusion criteria
1. BMI less than 27 kg/m^2
2. Other concurrent medical conditions
3. Ongoing use of the OCP
4. Pregnancy or desire for pregnancy
4. Secondary causes of amenorrhoea and hyperandrogenism

Date of first enrolment
01/10/2002

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Australia

Study participating centre
Monash Institute of Health Services Research
Melbourne
Australia
3168

Sponsor information

Organisation
Southern Health (Australia)

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Sponsor type
Government

Website
http://www.southernhealth.org.au

Funder(s)

Funder type
Industry

Funder Name
Pfizer (Australia) - competitive cardiovascular lipid grant 2003 and internal departmental fund

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/03/2007		Yes	No