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Randomised trial comparing a Low Carbohydrate Diet and a Low Glycaemic Index Diet on body weight, hyperandrogenism and cardiovascular risk factors in women with Polycystic Ovary Syndrome (PCOS)

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
06/04/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0199129935

Study information

Scientific Title

Study objectives
Does a low carbohydrate high protein diet enhance weight loss and improve symptoms in women with polycystic ovary syndrome (PCOS)? Assessment of the effects of the low carbohydrate diet on serum androgens and cardiovascular risk factors such as insulin sensitivity and plasma lipids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised case-controlled prospective study

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Polycystic ovarian syndrome (PCOS)

Interventions
Low Carbohydrate Diet vs Low Glycaemic Index Diet

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Weight, body composition, dietary compliance, menstrual cyclicity, ovulation, fasting glucose, insulin and lipids, hirsutism and serum androgens

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/04/2007

Eligibility

Key inclusion criteria
60 women with PCOS aged 18-45

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/07/2003

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Diabetes & Endocrinology
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Royal Berkshire and Battle Hospitals NHS Trust (UK)

Results and Publications

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?
Abstract results	results published			No	No