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	Recruitment status No longer recruiting	Prospectively registered		
30/09/2004		Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
06/04/2011	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised case-controlled prospective study

Primary study design

Interventional

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