

# 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

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

30/09/2004

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

06/04/2011

**Condition category**

Nutritional, Metabolic, Endocrine

☐ 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

### 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? |
|----------------------------------|-------------------|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a> | results published |              |            | No             | No              |