

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Weight, body composition, dietary compliance, menstrual cyclicity, ovulation, fasting glucose, insulin and lipids, hirsutism and serum androgens

Secondary outcome measures

Not provided at time of registration

Overall study start date

30/07/2003

Completion date

30/04/2007

Eligibility**Key inclusion criteria**

60 women with PCOS aged 18-45

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

60

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

England

United Kingdom

Study participating centre

Centre for Diabetes & Endocrinology

Reading

United Kingdom

RG1 5AN

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

Royal Berkshire and Battle 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results published			No	No