

Low fat versus low carbohydrate weight reduction diets: evaluation of effects on insulin resistance and cardiovascular risk

Submission date
07/12/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/02/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/09/2009

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Steven Hunter

Contact details

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Additional identifiers

Protocol serial number

RGHT000222

Study information

Scientific Title

Study objectives

The traditional low fat/high carbohydrate diet has beneficial effects on factors linked to the risk of diabetes and atherosclerosis compared to a high fat/low carbohydrate diet.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethically approval has been granted by the Office for Research Ethics Committees in Northern Ireland (ORECNI) (ref: 05/NIR01/142).

Primary study design

Interventional

Study design

The study is a randomised, controlled intervention study.

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Obesity

Interventions

The volunteers will be randomised to either a low fat or a low carbohydrate diet for eight weeks. All food for the duration of the diet will be provided. All assessments below will be carried out at baseline and again at the end of the diet.

Insulin resistance will be assessed by the hyperinsulinaemic euglycaemic clamp. Body composition will be measured using DEXA scanning and bioelectrical impedance. Pulse wave analysis will be done to assess vascular compliance. A meal tolerance test will be done to measure pancreatic function. Subcutaneous adipose tissue samples will be collected to measure mRNA expression of hormones. Lipid profile, HbA1c, adipocytokine levels and blood pressure will also be measured.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Assessment of insulin sensitivity by hyperinsulinaemic euglycaemic clamp

Key secondary outcome(s)

1. Body weight and composition
2. Assessment of blood pressure
3. Lipids
4. Vascular compliance
5. Adipocytokine levels
6. Pancreatic function

Completion date

31/07/2007

Eligibility

Key inclusion criteria

1. Male and female healthy volunteers
2. Aged 18 to 65
3. Body Mass Index (BMI) greater than 27

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. History of diabetes
2. coronary, hepatic or renal disease
3. Pregnancy

Date of first enrolment

02/10/2005

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Study participating centre

Regional Centre for Endocrinology and Diabetes

Belfast

United Kingdom

BT12 6BA

Sponsor information

Organisation

Royal Group of Hospitals (UK)

ROR

<https://ror.org/03rq50d77>

Funder(s)

Funder type

Industry

Funder Name

The Sugar Bureau (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?
Results article	results	01/12/2009		Yes	No