ISRCTN85769730 https://doi.org/10.1186/ISRCTN85769730

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
Registration date 21/02/2007	**Overall study status** Completed
Last Edited 03/09/2009	**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

Contact name
Dr Steven Hunter

Contact details
Regional Centre for Endocrinolgy and Diabetes
Level 1, Royal Victoria Hospital
Belfast
United Kingdom
BT12 6BA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
The study is a randomised, controlled intervention study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

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 impedence. Pulse wave analysis will be done to assess vascular compliance. A meal tolerence test will be done to measure pancreatic function. Subcutaneous adipose tissue samples will be collected to measure mRNA expression of hormones. Lipid profile, HBA1c, adipocykine levels and blood pressure will also be measured.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Assessment of insulin sensitivity by hyperinsulinaemic euglycaemic clamp

Secondary outcome measures
1. Body weight and composition
2. Assessment of blood pressure
3. Lipids
4. Vascular compliance
5. Adiopcykine levels
6. Pancreatic funtion

Overall study start date
02/10/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 volunteers

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
Northern Ireland

United Kingdom

Study participating centre
Regional Centre for Endocrinolgy and Diabetes
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Royal Group of Hospitals (UK)

Sponsor details
Royal Victoria Hospital
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.royalhospitals.org/

ROR
https://ror.org/03rq50d77

Funder(s)

Funder type
Industry

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