ISRCTN09001687 https://doi.org/10.1186/ISRCTN09001687

How does dietary carbohydrate influence the formation of an atherogenic lipoprotein phenotype?

Submission date	Recruitment status
19/05/2010	No longer recruiting
Registration date	**Overall study status**
19/05/2010	Completed
Last Edited	**Condition category**
23/05/2022	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
Prof Bruce Griffin

Contact details
Faculty of Health and Medical Science
Guildford
United Kingdom
GU2 7XH

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT01790984

Protocol serial number
6517

Study information

Scientific Title
How does dietary carbohydrate influence the formation of an atherogenic lipoprotein phenotype?

Acronym
DRN 270 Carbohydrate and Lipoproteins

Study objectives
Despite the falling trend in death from cardiovascular disease (CVD) in the UK in the last 10 years, the morbidity in CVD is increasing exponentially as a direct result of the cardio-metabolic risk arising from obesity, metabolic syndrome and type 2 diabetes. One of the key public health nutritional strategies to prevent this from happening is to replace dietary fat, principally saturated fat, with carbohydrate, to reduce such risk factors as serum low density lipoprotein (LDL) cholesterol. However, meta-analyses have firmly established that replacing dietary fat with carbohydrate is not associated with a decrease in CVD risk. Moreover, when the amount and quality of carbohydrate is uncontrolled, an exchange of fat for carbohydrate can increase risk arising from the insulin-resistant conditions described above. Recent evidence suggests that this adverse effect of dietary carbohydrate on CVD risk can be ameliorated by controlling the quality of carbohydrate; this may be achieved by limiting intake of non-milk extrinsic sugars (fructose and sucrose) and increasing non-starch polysaccharides (NCP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 08/H1109/227

Study design
Single-centre randomised interventional process of care trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Other; Disease: Cardiovascular disease

Interventions
The study will be a randomised, dietary intervention with a cross-over design. It will examine the effect of two test diets for 12 weeks, that differ in the quality of carbohydrate (high and low non-milk extrinsic sugars [NMES]), in two groups of subjects at risk of metabolic syndrome but with different proportions of liver fat (low liver fat less than 2% and moderate liver fat greater than 10% but less than 20%). The test diets will be preceded by a 4-week run-in diet and separated by 4 weeks of wash-out.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Formation of high- and low-risk lipoprotein phenotypes

Key secondary outcome(s))
1. LDL kinetics, with a focus on the formation of small dense LDL
2. Sources of liver fat
3. Whether VLDL-TG is derived from increased DNL and/or systemically derived NEFA
4. VLDL kinetics, with focus on differential effects on the synthesis of VLDL-TG and VLDL-apoB

Completion date
01/09/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2009

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Faculty of Health and Medical Science
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

ROR
https://ror.org/00cwqg982

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, Biotechnology and Biological Sciences Research Council (BBSRC), BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/05/2021	23/05/2022	No	No