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

Submission date	Recruitment status	Prospectively registered
19/05/2010	No longer recruiting	[_] Protocol
Registration date	Overall study status	Statistical analysis plan
19/05/2010	Completed	[X] Results
Last Edited 23/05/2022	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 Prof Bruce Griffin

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

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number NCT01790984

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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 nonmilk 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 measure

Formation of high- and low-risk lipoprotein phenotypes

Secondary outcome measures

- 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

Overall study start date

01/04/2009

Completion date 01/09/2011

Eligibility

Key inclusion criteria Not provided at time of registration

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants Planned sample size: 36; UK sample size: 36

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 England

United Kingdom

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)

Sponsor details Research & Development Polaris House Polaris Way Swindon United Kingdom SN2 1UH

Sponsor type Research council

Website http://www.bbsrc.ac.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, BBSRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details
Basic results	

Date created 27/05/2021

Date added 23/05/2022 **Peer reviewed?** No

Patient-facing? No