

Impact of the amount and composition of dietary fat and carbohydrate on metabolic syndrome and cardiovascular disease risk

Submission date 16/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/08/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.risck.org.uk>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NO2031

Study information

Scientific Title

Acronym

RISCK

Study objectives

To test whether the replacement of saturated fat (SFA) with monounsaturated fat (MUFA), compared with carbohydrate (CHO), will result in improved insulin sensitivity in adults with features of the metabolic syndrome; and whether CHO quality will influence the relative health impact of both the MUFA-rich and CHO-rich diet regimens.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Metabolic syndrome and cardiovascular disease risk

Interventions

Comparison of four experimental diets (high MUFA, high glycemic index [GI]; high MUFA, low GI; low fat, high GI; low fat, low GI) with a control group (SFA intake typical of the UK habitual diet)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Saturated fat (SFA), monounsaturated fat (MUFA), carbohydrate (CHO)

Primary outcome measure

Insulin sensitivity from measures of glucose and insulin during an intravenous glucose tolerance test.

Secondary outcome measures

1. Fasting lipid profile
2. Vascular reactivity and endothelial function
3. Haemostatic factors
4. Markers of the inflammatory response
5. Leptin and adiponectin
6. Urinary microalbumin to creatinine ratio
7. Plasma fatty acid composition
8. DNA for nutrient-gene interactions

Overall study start date

01/01/2004

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Males and females, 30-70 years and at higher metabolic risk (based on a composite scoring system for metabolic syndrome features).

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

650

Key exclusion criteria

1. History of the following conditions/treatments
 - 1.1. myocardial infarction
 - 1.2. cancer

- 1.3. diabetes mellitus
- 1.4. cholestatic liver disease or pancreatitis
- 1.5. chronic coronary, renal or bowel disease
- 1.6. gastrointestinal disorders
- 1.7. hypolipidemic therapy
- 1.8. systemic corticosteroids
- 1.9. androgens
- 1.10. phenytoin
- 1.11. erythromycin
- 1.12. haemostatic drugs (excluding aspirin)
2. Smokers >20/day
3. History of substance abuse or alcoholism
4. Pregnancy, planning pregnancy or 12-months post-partum
5. Allergy or intolerance to study foods
6. Recent weight change
7. Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) >1 g/day

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Human Nutrition Research

Cambridge

United Kingdom

CB1 9NL

Sponsor information

Organisation

MRC Human Nutrition Research (UK)

Sponsor details

Elsie Widdowson Laboratory

Fulbourn Road

Cambridge
United Kingdom
CB1 9NL

Sponsor type

Research council

ROR

<https://ror.org/050pqs331>

Funder(s)

Funder type

Not defined

Funder Name

Food Standards Agency (UK)

Alternative Name(s)

The Food Standards Agency, FSA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article	results	01/08/2009	Yes	No
Results article	results	01/10/2010	Yes	No
Results article	results	01/12/2011	Yes	No
Results article	results	01/02/2012	Yes	No
Results article	results	01/09/2013	Yes	No