ISRCTN35312139 https://doi.org/10.1186/ISRCTN35312139

Fermentation and cardiovascular risk factors

Submission date	Recruitment status	[_] Prospectively registered
07/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2012	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Denise Robertson

Contact details
Biomedical and Molecular Sciences
University of Surrey
Guildford
United Kingdom
GU2 7XH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NS1

Study information

Scientific Title

Study objectives
That consuming a fermentable carbohydrate will improve indices of insulin sensitivity in individuals with insulin resistance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Office of Research Ethics Committees (COREC) and the University of Surrey Ethics Committee, approved on 26th June 2006 (REC ref: O6/Q1909/30)

Study design
Randomised, parallel, single-blind dietary intervention.

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
Type 2 diabetes/ obesity

Interventions
Dietary supplementation with either 0 g, 20 g or 40 g resistant starch per day for 12 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
resistant starch

Primary outcome measure
Insulin sensitivity will be assessed before and after the 12-week intervention by the following:
1. Euglycaemic-hyperinsulinaemic clamp
2. Liver fat content measured by Magnetic Resonance Imaging [MRI]

Secondary outcome measures
The following outcomes are being measured before and after the 12-week intervention:
1. Endothelial function, assessed by Pulse Wave Velocity (PWV) and 24-hour blood pressure recordings
2. Blood inflammatory markers

Overall study start date
01/11/2006

Completion date
30/10/2008

Eligibility

Key inclusion criteria
1. Healthy
2. Fasting insulin >60 pmol/l
2. Male and female 18-60 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Cardiovascular or endocrine diseases
2. Medication likely to affects either lipid or glucose metabolism

Date of first enrolment
01/11/2006

Date of final enrolment
30/10/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Biomedical and Molecular Sciences
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Research and Enterprise Support
Nodus Centre
University of Surrey
Guildford
England
United Kingdom
GU2 7XH

Sponsor type
University/education

Website
http://www.surrey.ac.uk/

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Industry

Funder Name
National Starch and Chemical Company (International)

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	01/04/2010		Yes	No