

# Fermentation and cardiovascular risk factors

<b>Submission date</b> 07/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/02/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Denise Robertson

### Contact details

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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 affect 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?
<a href="#">Results article</a>	results	01/04/2010		Yes	No