

# Bacteria and glucose control

<b>Submission date</b> 11/04/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/04/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/01/2019	<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

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11066

## Study information

**Scientific Title**

Do gut bacteria have a role in the aetiology of type 2 diabetes?

**Study hypothesis**

Animal models have clearly demonstrated that gut bacteria can be linked to changes in the permeability of the intestine and may be responsible for some of the clinical features associated with type 2 diabetes. This will be the first attempt to translate these findings into human volunteers and patients.

The main objectives of this study are to

1. Assess whether colonic microflora, intestinal permeability, and endotoxaemia (plasma levels of lipopolysaccharide) in patients with type 2 diabetes differ from those of matched obese and lean subjects
2. To assess whether manipulation of colonic microflora with prebiotic carbohydrate supplement improves glucose tolerance via improvements in intestinal permeability and endotoxaemia.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

First MREC, 06/09/2011, ref: 11/LO/1141

**Study design**

Interventional randomised treatment trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

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

**Condition**

Diabetes Type 2

**Interventions**

We will recruit 30 patients with type 2 diabetes in addition to 30 healthy controls in which we will characterise gut bacteria, measure intestinal permeability non-invasively and look for signs of inflammation. For healthy subjects, this involves three visits to the Royal Surrey County hospital for screening and a blood test, permeability test (ingestion of <sup>51</sup>Cr-EDTA in water followed by 24h urine collection), and return of urine collection and a stool sample.

In addition in the patient group, we will use a 12-week dietary intervention using prebiotic fibre to directly change the bacterial composition, to investigate whether this has any beneficial effects on glycaemic control. Following the 3 visits for baseline measurements, which also includes an IVGTT test for insulin secretion for this group, the patients will be randomised to either prebiotic treatment (galacto-oligosachharide 5g/day) or placebo (maltodextrin 5g/day). On the completion of the dietary intervention, patients will return to the hospital for another two visits for an intestinal permeability test and return of 24 hour urine collection and a stool sample and an IVGTT test

Prebiotic, randomization to either prebiotic carbohydrate supplement 5g, or maltodextrin as a placebo, daily for 12 weeks.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Inflammatory markers measured at baseline and after 12 weeks intervention

### **Secondary outcome measures**

1. Gut bacteria measured at at baseline and after 12 week intervention
2. Insulin secretion measured at baseline and after 12 weeks intervention
3. Intestinal permeability measured at baseline and after 12 weeks intervention
4. Plasma endotoxin measured at baseline and after 12 weeks intervention

### **Overall study start date**

01/01/2012

### **Overall study end date**

30/09/2014

## **Eligibility**

### **Participant inclusion criteria**

1. Male
2. Aged 40-65
3. With or without Type 2 diabetes
4. Appropriate renal function

### **Participant type(s)**

Patient

### **Age group**

Neonate

### **Sex**

Male

**Target number of participants**

UK Sample Size: 60; Description: 30 control subjects and 30 patients with type 2 diabetes

**Participant exclusion criteria**

1. Female
2. History of bowel disease
3. Abnormal renal function
4. Use of antibiotics in preceding 3 months
5. Regular use of NSAID medication
6. Use of diuretics

**Recruitment start date**

01/01/2012

**Recruitment end date**

30/09/2014

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

University of Surrey

Guildford

United Kingdom

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**Sponsor information****Organisation**

University of Surrey (UK)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.surrey.ac.uk/>

**ROR**

<https://ror.org/00ks66431>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

European Foundation for the study of Diabetes (EU)

**Alternative Name(s)**

The European Association for the Study of Diabetes, EFSD

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Germany

## **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	01/12/2016	21/01/2019	Yes	No
<a href="#">Results article</a>	results of the potential link between glucose control, intestinal permeability, diet and intestinal microbiota in patients with Type 2 Diabetes,	01/04/2018	21/01/2019	Yes	No
<a href="#">Results article</a>	results of the potential relationship between gut barrier function (gut permeability) and concentration of serum lipids and lipoproteins,	01/12/2018	21/01/2019	Yes	No