

Bacteria and glucose control

Submission date 11/04/2012	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/04/2012	Overall study status Completed	☐ Protocol
Last Edited 21/01/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11066

Study information

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

Study objectives

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

Primary study design

Interventional

Study design

Interventional randomised treatment trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

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 ⁵¹Cr-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-oligosaccharide 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(s)

Inflammatory markers measured at baseline and after 12 weeks intervention

Key secondary outcome(s)

1. Gut bacteria measured 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

Completion date

30/09/2014

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Male

Key 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

Date of first enrolment

01/01/2012

Date of final enrolment

30/09/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Surrey

Guildford

United Kingdom

GU2 7DJ

Sponsor information

Organisation

University of Surrey (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, European Association for the Study of Diabetes (EASD), EFSD

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016	21/01/2019	Yes	No
Results article	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
Results article	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