ISRCTN07813749 https://doi.org/10.1186/ISRCTN07813749

Bacteria and glucose control

Submission date	Recruitment status
11/04/2012	No longer recruiting
Registration date	**Overall study status**
11/04/2012	Completed
Last Edited	**Condition category**
21/01/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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 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

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

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-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

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

Age group
Neonate

Sex
Male

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

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
England

United Kingdom

Study participating centre
University of Surrey
Guildford
United Kingdom
GU2 7DJ

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Wolfson Unit for Translational Research
Diabetes and Endocrinology
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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?

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