ISRCTN40517475 https://doi.org/10.1186/ISRCTN40517475

Biogut: a study of nutrient bioaccessibility in ileostomy volunteers

Submission date	Recruitment status	[X] Prospectively registered
31/05/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/09/2015	Digestive System	

Plain English summary of protocol

Background and study aims
Evidence shows that the structure and properties of plant foods, particularly of the cell wall component (dietary fibre), play an important role in regulating the release (bioaccessibility) of nutrients from plant foods during chewing and digestion. Cell walls may act as a physical barrier to the digestion of carbohydrate and/or fat thus attenuating the blood glucose or lipid response induced. In a meal, fat and/or starch availability can therefore be controlled by modifying the amount of the nutrients encapsulated by cell walls. Because glucose and lipid responses following the consumption of a meal are associated with reduced risk factors for type 2 diabetes mellitus and cardiovascular disease, this work has implications for the prevention and management of these diseases. The aim of this project is to investigate the effect of meals with various degree of bioaccessibility (amount of cell walls) on nutrient (lipid/starch) release in a group of ileostomy volunteers (removing the colon is called proctocolectomy and creating the opening to the intestine is called ileostomy).

Who can participate?
We are looking for 12 ileostomy volunteers, who are not allergic to almonds or any other ingredients incorporated in any of the test meals. To be eligible, you must be aged 20-60 years, previously had proctocolectomy, be stable for at least 12 months since you had your ileostomy, and have eaten almonds with no adverse effects.

What does the study involve?
Once we have checked your eligibility and you have given consent, we will ask you to attend a screening session and five study visits at the Clinical Research Facility of St Thomas' Hospital. The study visits are divided into two studies: Study 1 looking at fat release and Study 2 looking at starch release.
During the session (lasting between 13 and 14 hours) you will be given for breakfast either:
Study 1 (3 visits): 85 g of whole almonds given with a muffin and some custard, a muffin containing almond flour with some custard, or a muffin containing 2 mm almond pieces and some custard.
Study 2 (2 visits): porridge containing durum wheat flour and 300 ml water, or porridge containing 2 mm durum wheat large semolina and 300 ml water. Digestive products leaving the ileum (effluents) will be collected every 2 h up to 12 h and at your convenience in the evening

and overnight. Blood will also be collected (approximately 15 ml = 3 teaspoons) after the meals at different time intervals up to 8 hours for Study 1 and 4 hours for Study 2. The effluent samples produced will be used for nutrient analysis (lipid or starch), microscopy and particle sizing. Glucose and lipid levels will be measure in the collected blood samples.

What are the possible benefits and risks of participating?
Full biochemical, anthropometric and blood pressure screening will be available to all participants at the screening stage. Results will be available to all participants. We believe the risks to participants are minimal as the study involves everyday activities. Our main concern is that individuals who are allergic to nuts and have experienced obstruction of the stoma do not take part.

Where is the study run from?
The study is organised by researchers from King's College London and will take place at the Clinical Research Facility of St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start August/September 2012. Participants will be enrolled on the study for a period of 5/6 months.

Who is funding the study?
The Biotechnology and Biological Sciences Research Council (BBSRC), reference BB/H004866/1.

Who is the main contact?
Myriam Grundy, myriam.grundy@kcl.ac.uk
Cathrina Edwards, cathrina.edwards@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Sanderson

Contact details
4th Floor, Franklin Wilkins Building
Waterloo Campus
King's College London
150 Stamford Street
London
United Kingdom
SE1 9NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised trial to study nutrient bioaccessibility in ileostomy volunteers

Acronym
Biogut

Study objectives
Changing the structure/degree of processing of food ingredients will alter the amount of nutrients that is released (nutrient availability) when that food is eaten. Meals with a lower nutrient availability will generate a slower/smaller blood glucose or lipid response than the meals with a higher nutrient availability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC name: South East Coast - Kent, 27/06/2012, ref: 12/LO/1016

Study design
Randomised cross-over design trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

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
Digestion and nutrient bioaccessibility

Interventions
Participants will eat on 5 separate occasions the test meals rich in either fat (Study 1) or starch (Study 2):

Study 1 (3 visits)
1. 85 g of whole almonds given with a muffin and some custard
2. A muffin containing almond flour and almond oil with some custard
3. A muffin containing 2 mm almond pieces and some custard

Study 2 (2 visits)
1. Porridge containing durum wheat flour and 300 ml water
2. Porridge containing 2 mm durum wheat large semolina and 300 ml water

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Indicative measure of the digestibility (nutrient loss and modification in cell wall structure) of fat or starch foods during passage throught the upper gastrointestinal tract

Secondary outcome measures
1. Measuring the glycaemic and lipaemic response to the test meals including insulin and c-peptide
2. Measuring the particle size of chewed and digested samples
3. Examination of the microstructure of chewed and digested samples
4. Measuring gut hormones [peptide YY (PYY), cholecystokinin (CCK), glucagon-like peptide-1 (GLP-1) and gastric inhibitory polypeptide (GIP)]

For Study 1, plasma triacylglycerol concentrations will be measured hourly up to 8 h to determine the overall level of lipaemia after eating the test meal. Plasma glucose and insulin will also be measured at 0, 15, 30, 45, 60, 90, and 120 min and thereafter at 3, 4, 5, 6, 7, and 8 h.

For Study 1 and 2, plasma glucose and insulin concentrations will be measured at 0, 15, 30, 45, 60, 90, 120, 150 min and at hourly intervals up to 4 h, to determine blood glucose and insulin levels after eating the test meal.

Overall study start date
03/09/2012

Completion date
08/02/2013

Eligibility

Key inclusion criteria
1. Male or female aged 20-60 years, who previously had proctocolectomy
2. Stable at least 12 months post-operative
3. Normal stoma functions (digest and excrete food without any difficulty)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Allergy to almonds or related products, gluten and any other added ingredients in recipe of the test meal
2. Previous case of obstruction of the stoma
3. Body mass index < 20 kg/m2 or > 35 kg/m2
4. Have a diagnosed mouth, throat or gastrointestinal tract problem (other than ileostomy) that may affect normal ingestion and digestion of food
5. Plasma glucose > 7 mmol/L
6. Plasma cholesterol > 7.8 mmol/L
7. Plasma triacylglycerol > 3 mmol/L
8. On a medication regimen that would invalidate the results as judged by the medical advisor

Date of first enrolment
03/09/2012

Date of final enrolment
08/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Research Facility of St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Mr Keith Brennan
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council (BBSRC) (UK) ref: BB/H004866/1

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/10/2015		Yes	No