ISRCTN90225764 https://doi.org/10.1186/ISRCTN90225764

The effect of fermentable carbohydrates on appetite - version 1

Submission date	Recruitment status	[X] Prospectively registered
04/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/10/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
High fibre diets are known to be related to a number of health benefits and have been widely advertised (in breakfast cereals, for example) as a way of helping people to lose weight. Short chain fatty acids, one of the breakdown products of fibre, may be responsible for the beneficial effects of fibre. One specific short chain fatty acid, propionate, may be associated with a reduction in feelings of hunger. Different dietary fibres produce different amounts of propionate. It is currently unknown which dietary fibres produce the largest amounts of propionate and whether they affect appetite (i.e. how hungry or full you feel). The aim of this study is to find out the effects of a range of dietary fibres on propionate levels and appetite. This may be important in terms of controlling body weight and therefore preventing obesity.

Who can participate?
Healthy men and women, aged 18-65, who are either normal weight or overweight

What does the study involve?
There are two parts to this study. Part A and B both consist of three separate study visits. In Part A, on the study days participants receive a standard breakfast containing 25g of one of three food supplements and two non-radioactive tracer molecules, which are used to track the digestive process. A standard snack and meal is also provided. Participants complete questionnaires to measure appetite, and breath and blood samples are collected. In Part B, participants are instructed to consume one of the three dietary supplements from Part A in an increased dose for 7 days before each of the three study visits. On study days, participants consume a standard breakfast, which contains 25 g of the same dietary supplement that they have been taking. A snack and buffet meal are also provided. The following measurements are collected: amount of propionate in blood, appetite ratings using questionnaires, food intake at a buffet meal (where participants are instructed to eat until they feel comfortably full) and breath hydrogen samples.

What are the possible benefits and risks of participating?
Volunteers will not benefit directly from this study but the results may help doctors in the future treat patients with obesity. Some of the procedures in this study, such as the recording of your weight, height and blood pressure, and the collection of breath samples, present no risk.

Taking blood samples can cause mild discomfort when the needle is inserted, and possible bruising and infection in that area. These procedures will only be carried out by experienced healthcare professionals under germ-free conditions in order to minimise such risks. As with any high fibre diet, volunteers may experience tummy bloating and discomfort. There is also a small chance that volunteers may experience episodes of diarrhoea during the study. In order to minimise the risk of this happening, in Part B the total dose of dietary supplement being consumed will be increased slowly over the course of the 7 days before each study visit. Volunteers may also find the taste of the dietary supplements unpleasant and so will be advised on the best way to add it into your diet. The addition of the dietary supplement to their daily routine will be an inconvenience and will require a change in lifestyle. To minimise inconvenience, all supplements will be provided in ready-to-use sachets.

Where is the study run from?
Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2014 to July 2015

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
Miss Claire Byrne
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Contact information

Type(s)
Scientific

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Protocol serial number
16769

Study information

Scientific Title
The effect of short-term dietary supplementation of fermentable carbohydrates on propionate production and appetite measures: a pilot study

Study objectives
The aim of this study is to investigate whether short-term dietary supplementation of fermentable carbohydrate (FC) increases plasma propionate concentrations and suppresses appetite in humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London Harrow, 16/06/2014, ref. 14/LO/0704

Study design
Randomised single-blind cross-over feeding study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Current interventions as of 11/10/2017:
This will be a study comparing the effects of L-rhamnose on appetite and plasma propionate concentrations, with inulin and cellulose. This study will involve three separate 7-day feeding periods followed by study days, with a 2-week wash-out period between study visits. This study will be preceded by a protocol optimisation study, which will involve three separate study visits. Inulin will be used as a positive control (as we know it is fermented in the colon) and cellulose as a negative control (as we know it does not ferment significantly in the colon) in both studies. Two studies are proposed: an optimisation study to assess the effect of FCs on gut transit time and therefore optimise sampling regimens, and a feeding study to assess the effect of FCs on appetite.

In the Optimisation Study, participants will consume 25 g of one of the three dietary supplements on each of the three study days according to their randomisation pattern.

In the Feeding Study, participants will consume a different dietary supplement in a stepped dose for 7 days prior to each one of the three study visits (final daily dose 25 g). On study days, volunteers will receive 25 g of the appropriate dietary supplement with their breakfast.

Randomisation will be conducted by sealed envelopes once the participants have successfully passed the health screening. The participants will be blinded as to the type of supplement they are taking.

Previous interventions:
This will be a study comparing the effects of B-glucan (fermentable, soluble and viscous) on appetite and plasma propionate concentrations, with inulin (fermentable, soluble and non-viscous), cellulose (non-fermentable, insoluble and non-viscous) and methyl cellulose (non-fermentable, soluble and viscous). This study will involve four separate 7-day feeding periods followed by study days, with a 2-week wash-out period between study visits. This study will be preceded by a protocol optimisation study, which will involve four separate study visits. Inulin will be used as a positive control (as we know it is fermented in the colon) and cellulose as a negative control (as we know it does not ferment significantly in the colon) in both studies. The addition of methyl cellulose (a non-fermentable, soluble and viscous product) as a fourth leg to both studies will allow for the assessment of the effect of viscosity on appetite measures. Two studies are proposed: an optimisation study to assess the effect of FCs on gut transit time and therefore optimise sampling regimens, and a feeding study to assess the effect of FCs on appetite.

In the Optimisation Study, participants will consume 10 g of one of the four dietary supplements on each of the four study days according to their randomisation pattern.

In the Feeding Study, participants will consume a different dietary supplement in a stepped dose for 7 days prior to each one of the four study visits. Participants will consume 10 g of the appropriate dietary supplement on day 1, two 10 g servings on days 2-3 (total daily dose 20 g), and three 10 g servings on days 4-7 (total daily dose 30 g). On study days, volunteers will receive 10 g of the appropriate dietary supplement with their breakfast. The maximum dose used in this study is based on previous work carried out by our research group.

Randomisation will be conducted by sealed envelopes once the participants have successfully passed the health screening. The participants will be blinded as to the type of supplement they are taking.

Intervention Type
Supplement

Primary outcome(s)
Appetite; Timepoint(s): measures every 30 minutes over the study period

Key secondary outcome(s))
1. 13CO2 enriched breath hydrogen; Timepoint(s): measure every 30 minutes over the time period
2. Plasma propionate; Timepoint(s): measured every 30 minutes over the study period

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Body Mass Index (BMI) 20-35 kg/m2
2. Age 18-65

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
Any gastrointestinal disease

Date of first enrolment
01/08/2014

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR/Wellcome Trust Imperial CRF
Imperial Centre for Translational and Experimental Medicine
Imperial College Healthcare NHS Trust
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation

Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) - Clinical Trials Unit (CTU)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/08/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes