ISRCTN46403895 https://doi.org/10.1186/ISRCTN46403895

Investigation of the effects of slow release carbohydrate digestion on satiety and related blood biomarkers of satiety and energy release

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/11/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/12/2013	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
REC/10/0013

Study information

Scientific Title
Investigation of the effects of slow release carbohydrate digestion on satiety and related blood biomarkers of satiety and energy release: A randomised, double blinded, crossover trial

Study objectives
Consumption of slow carbohydrate digestion will influence satiety, related blood biomarkers of satiety and energy release, and subsequent food intake

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Ulster Research Ethics Committee approved on the 23rd of May 2010 (REC/10 /0013)

Study design
Randomised double blind crossover group trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Food metabolism

Interventions
Each patient will undergo each of the following conditions on the same day of each week and with a minimum one week interval between study conditions:
1. Control (rapidly digestible starches)
2. 10g slow digestible starch
3. 25g slow digestible starch
The order in which the patient undergoes these conditions will be randomised.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Food and nutrient intake:
1. Energy intake (kJ)
2. Macronutrient intakes (g and % energy)
3. Weight of food and beverages (g) consumed
Assessed following a test meal served 4 hours after consuming each of the test products.

Key secondary outcome(s))
1. Subjective satiety ratings:
Visual analogue scales (VAS) to assess feelings of hunger, fullness, thirst, preoccupation with thoughts of food and desire to eat will be made on each study condition
2. Hormonal and metabolic responses:
Blood samples will be taken at each study condition by venous cannula and analysed for the following metabolites:

2.1. Glucose
2.2. Insulin
2.3. Glucagon-Like Peptide (GLP-1)
2.4. Ghrelin
2.5. Peptide YY (PYY)
(GLP-1, Ghrelin, and PYY only being analysed if there is a positive outcome for the outer measures)

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Aged between 19-55 years
2. Body Mass Index (BMI) > 20 and < 25
3. In good health condition (no cardiovascular, respiratory, neurological or metabolic disease such as diabetes)
4. Willing to consume the test products

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Regular use of medication (apart from OTC medication)
2. Smoking

Date of first enrolment
01/06/2010

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Northern Ireland Centre for Food and Health
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
University of Ulster (UK)

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Industry

Funder Name
Nestle (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration