Plasma glucagon-like peptide (GLP) (7-36) amide response to low versus high glycaemic index drinks in Type II diabetic subjects and nondiabetic controls.

Submission date 30/09/2004	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/09/2004	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 10/03/2011	Condition category Nutritional, Metabolic, Endocrine	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 N0016132030

Study information

Scientific Title

Study objectives

 To investigate the effects of drinks of differing glycaemic index (GI) on plasma GLP-1 concentrations and subsequent metabolic responses to a meal.
 To determine if a low GI drink will cause a greater increase in postprandial GLP-1 concentrations and result in improved metabolic response compared to a high GI drink or water at a subsequent meal.

Ethics approval required

Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Nutritional, Metabolic, Endocrine: Diabetes

Interventions Not provided at time of registration

Intervention Type Other

Phase Not Specified

Primary outcome measure

Diet is the first line treatment for Type 2 diabetes, however the optimal diet to promote good glycaemic control is still debated. GLP-1 is being investigated as an agent for the treatment of diabetes, however it has its shortcomings due to its short half life in humans. A specific food that could be consumed before a meal to stimulate release of GLP-1 and thus improve glycaemic control would be highly beneficial to patients, and potentially have fewer side effects and be less invasive than subcutaneous administration of the hormone.

Secondary outcome measures

Not provided at time of registration

Overall study start date 10/09/2003

Completion date 09/09/2007

Eligibility

Key inclusion criteria 1. 12 diabetics and 12 healthy volunteers 2. Ages 30-65

Participant type(s) Healthy volunteer

Age group Adult

Sex Not Specified

Target number of participants 24

Key exclusion criteria Not provided at time of registration

Date of first enrolment 10/09/2003

Date of final enrolment 09/09/2007

Locations

Countries of recruitment England

United Kingdom

Study participating centre Nutrition and Dietetics Department London United Kingdom W12 0HS

Sponsor information

Organisation Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name Hammersmith Hospital NHS Trust (UK)

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?
<u>Results article</u>	results	01/12/2007		Yes	No