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Effects of Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) on insulin secretion and energy balance in human obesity and diabetes

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 28/09/2011	**Condition category** Nutritional, Metabolic, Endocrine	

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
N0207174689

Study information

Scientific Title

Study objectives
1. Are both GIP and GLP-1 necessary for optimal insulin secretion in healthy and diabetic subjects?
2. Do both GIP and GLP-1 have an effect on energy balance and appetite?

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)
Diagnostic

Participant information sheet

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

Interventions
At the baseline assessment visit, eligibility will be confirmed, subjects will be weighed, height recorded, and waist circumference measured. Body composition will be measured by electrical bio impedance (Tanita 310). Thereafter, 4 half day studies are required for measurements of insulin secretion during infusion of GLP-1 alone, GIP alone, GLP-1 and GIP together and placebo. Because GLP-1 and GIP augment glucose-stimulated insulin secretion will be determined in response to co-infusion of 10% glucose during each experiment by serial blood sampling. Throughout these experiments, resting metabolic rate will be measured at baseline and then hourly (for postprandial thermogenesis) by indirect calorimetry, using the Deltatrack II system. Effects on hunger and satiety will be determined from concomitant visual analogue hunger scores taken at baseline and then hourly. Ad libitum food intake will be assessed with test meal

at lunchtime. The studies will be completed once lunch is consumed. A total of 48 studies will be undertaken. GLP-1/GIP peptides: GLP-1 and GIP has been obtained from Polypeptide Laboratories (Germany) and sterile-filtered by Stockport Pharmaceuticals (Stebbing Hill Hospital, Stockport). In preliminary work with synthetic peptides in non diabetic subjects we have found infusion of GLP-1 at rates of 1pmol/kg/min to be well tolerated without side effects, and to result in highly significant and sustained elevations in plasma insulin and C peptide concentrations. Steady states of insulin are reached after 60 minutes of infusion at this rate. Glucose profiles in plasma were maintained in the euglycaemic range during the combined infusion of dextrose and GLP-1 (unpublished).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP)

Primary outcome measure
Role of GIP and GLP-1 in diabetes and obesity

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
01/09/2006

Eligibility

Key inclusion criteria
Obese male subjects between age 20-60 years will be recruited by advertisement and by invitation of eligible patients who have already undergone glucose tolerance testing. This is a pilot study and will involve the following groups. 6 lean (BMI 20-25 kg/m2) subjects with normal glucose tolerance and 6 obese (BMI >30 kg/m2) type-2 diabetic patients on treatment with diet alone. Eligible subjects will be asked to provide informed written consent, and studies will be undertaken in accordance with the Declaration of Helsinki.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
6

Key exclusion criteria
Any co-morbid conditions requiring drug therapy that cannot be discontinued, any regular drug treatment that cannot be discontinued, any diseases of the heart, lungs, liver, gut or endocrine glands, alcoholism, eating disorder, and for the diabetic group - poorly controlled diabetes (defined as HbAlc >8.0% for the purposes of this study)

Date of first enrolment
01/09/2004

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept. of Clinical Chemistry
Liverpool
United Kingdom
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website

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

Funder(s)

Funder type
Government

Funder Name
Royal Liverpool and Broadgreen University Hospitals Trust (UK), RLUH R&D Trust Fund,

Funder Name
NHS R&D Support Funding.

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	01/08/2009		Yes	No