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

#### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr L R Ranganath

#### **Contact details**

Dept. of Clinical Chemistry Royal Liverpool University Hospital Prescot Street Liverpool United Kingdom L7 8XP +44 0151 706 4197 Irang@liv.ac.uk

## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N0207174689

## Study information

Scientific Title

Study objectives1. 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 L7 8XP

### Sponsor information

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

#### Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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?
<u>Results article</u>	results	01/08/2009		Yes	No