# The effect of ghrelin on gastric emptying in gastroparesis

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
12/09/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2003	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/10/2017	Digestive System			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0515129608

# Study information

#### Scientific Title

Ghrelin enhances gastric emptying in diabetic gastroparesis: a double blind, placebo controlled, crossover study.

#### **Study objectives**

We hypothesise that ghrelin stimulates gastric emptying in man. We aim to investigate whether ghrelin infusion can stimulate gastric emptying and provide a potential future treatment for diabetic gastroparesis.

Information will also be obtained about:

- 1. Safety of intravenous ghrelin in insulin-dependent diabetes mellitus (IDDM) patients
- 2. Correlating gastric emptying with autonomic function
- 3. Baseline serum ghrelin levels in Type I diabetic patients

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Double blind placebo controlled randomised cross-over study

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Digestive System: Gastroparesis

#### Interventions

At time zero infusion will commence with either 5 pmol/kg min ghrelin or saline. This will be blinded to both patient and doctor administering the infusion. Throughout the infusion, euglycaemia will be maintained using a glycaemic clamp. Patients will omit their usual morning dose of insulin on the day of the study, since they will be fasted. Gastric emptying and accommodation will be assessed with 3D real time ultrasound scanning.

Thirty minutes after the infusion has begun the subject will be given a meal of warm chicken soup and ultrasound measurements taken of the antrum and fungus taken at baseline and then 15 minutes intervals. From this the cross sectional areas can be calculated and hence the degree of gastric emptying. Small bowel transit will be calculated using the method of O'Brien et al.

Blood Glucose Monitoring (BM stix) measurements will then be made every 15 minutes during the infusion to help maintain euglycaemia. 8 ml of the venous blood will be drawn immediately before the infusion, and then at 15 minutes intervals until the end of the infusion. These samples will be spun down and frozen for subsequent analysis.

Blood pressure and heart rate will be recorded at 15-minute intervals throughout the study. Cardiac monitoring will continue through the whole infusion and for 30 minutes afterwards. Each subject will be asked to fill out the following questionnaires before commencement of infusion:

- 1. A visual analogue scale asking them to grade their upper GastroIntestinal (GI) symptoms and degree of hunger at 30 min intervals.
- 2. Gastric emptying data will be compared between placebo and ghrelin and for each subject using the paired Student t-test.
- 3. Non-parametric questionnaire data will be analysed using the Mann-Whitney U test.

#### Intervention Type

Drug

#### **Phase**

**Not Specified** 

# Drug/device/biological/vaccine name(s)

Ghrelin

#### Primary outcome measure

Not provided at time of registration

#### Secondary outcome measures

Secondary endpoints include:

- 1. Alleviation of hunger scores
- 2. Improvement of nausea scores
- 3. Changes in orocaecal transit

#### Overall study start date

01/02/2003

#### Completion date

09/09/2007

# Eligibility

#### Key inclusion criteria

We will recruit 16 patients with type I diabetes mellitus from the Northwick Park Diabetic Cohort who have symptoms compatible with gastroparesis, aged 18-80 years old.

### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

## Upper age limit

80 Years

#### Sex

Both

# Target number of participants

16

# Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/02/2003

# Date of final enrolment

09/09/2007

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre

**University College Hospital** 

Department of Gastroenterology and Nutrition London United Kingdom NW1 2BU

# Sponsor information

#### Organisation

Department of Health (UK)

# Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

Website

http://www.doh.gov.uk

# Funder(s)

## Funder type

Government

#### Funder Name

North West London Hospitals 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?
Results article	results	01/12/2005		Yes	No