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# The effect of ghrelin on gastric emptying in gastroparesis

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

**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**
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

## Primary study design
Interventional

## Study design
Double blind placebo controlled randomised cross-over study

## Study type(s)
Treatment

## 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(s)
Not provided at time of registration

### Key secondary outcome(s)
Secondary endpoints include:
1. Alleviation of hunger scores
2. Improvement of nausea scores
3. Changes in orocaecal transit

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
80 Years

### Sex
All

### 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**
United Kingdom

England

**Study participating centre**
**University College Hospital**
Department of Gastroenterology and Nutrition
London
United Kingdom
NW1 2BU

# Sponsor information

**Organisation**
Department of Health (UK)

# Funder(s)

**Funder type**
Government

**Funder Name**
North West London Hospitals NHS Trust (UK)

# Results and Publications

**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 |