

The effect of ghrelin on gastric emptying in gastroparesis

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2017	Condition category Digestive System	<input type="checkbox"/> 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

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

Study design

Double blind placebo controlled randomised cross-over study

Primary study design

Interventional

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 fundus 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 oro-caecal 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