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The effect of ghrelin on gastric emptying in gastroparesis

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] 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

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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