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A randomized, double-blind, placebo-controlled, multicenter trial to evaluate the clinical efficacy of a single intrapyloric injection of botulinum toxin type A (Botox®) in patients with idiopathic gastroparesis. The BIG study.

Submission date 09/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/06/2006	**Overall study status** Completed	
Last Edited 09/06/2006	**Condition category** Nutritional, Metabolic, Endocrine	

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
P05.170

Study information

Scientific Title

Acronym
BIG study

Study objectives
Several open-label pilot studies have shown a promising effect of intrapyloric botulinum toxin injection on symptoms in severe gastroparesis. However, data from randomized, double-blind, placebo-controlled studies are not yet available. We intend to evaluate the clinical efficacy of a single intrapyloric injection of botulinum toxin type A in patients with idiopathic gastroparesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A randomized, double-blind, placebo-controlled, multicenter trial

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
Idiopathic gastroparesis

Interventions
Intrapyloric injection of botulinum toxin type A 200 IU single injection or placebo single injection. Scintigraphy for solid/liquid gastric emptying (before and after treatment).

Gastroparesis cardinal symptom index questionnaire
Quality of life (QOL) questionnaires
Psychometric assessment and patient perception questionnaires

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin

Primary outcome measure
Gastric emptying for solids.
1. Half-emptying time at visit 4 (follow-up: week 6) compared to visit 1b (eligibility: week 1)
2. Emptying rate per hour at visit 4 (follow-up: week 6) compared to visit 1b (eligibility: week 1)
3. One, two and four hour meal retention at visit 4 (follow-up: week 6) compared to visit 1b (eligibility week 1).
Gastroparesis cardinal symptom index (GCSI) outcome
4. Total GCSI score at visit 3, 4, 5 and 6 (follow-up: week 3, 6, 9 and 12) compared to visit 2 (randomization: week 0)
5. Mean GCSI score during follow-up (week 0-12) compared to mean GCSI score during eligibility and randomization (week 10)

Secondary outcome measures
1. Gastric emptying for liquids; retention of liquid phase at 15, 30, 45, 60, 75, 90, 105 and 120 min
2. Quality of life as measured with the patient assessment of upper gastrointestinal disorders - quality of life (PAGI-QoL), the RAND-36 and EQ-5D questionnaires
3. Psychometric assessment and patient perception of gastrointestinal endoscopy

Overall study start date
01/06/2006

Completion date
01/06/2007

Eligibility

Key inclusion criteria
Patients are eligible to participate in this study if all of the following criteria are met:
1. Presence of clinical symptoms associated with idiopathic gastroparesis: nausea, vomiting, early satiety, postprandial fullness and a Gastroparesis Cardinal Symptom Index (GCSI) score ≥1 at visit 1b (eligibility; week 1)
2. Delayed gastric emptying for solids at visit 1b (eligibility; week 1) as measured with scintigraphy:
a. 2h retention ≥60%; and/or
b. 4h retention ≥10%
3. Absence of an obstructing structural lesion in the stomach or small intestine at prior diagnostic gastrointestinal endoscopy (performed within the previous 5 years) or judged absent

by the responsible physician
4. Patients, both male and female, must use adequate means of birth control during the study
5. Patients must provide written informed consent prior to any study procedures being performed
6. Patients aged between 18 and 70 years inclusive
7. Patients, in the opinion of the investigator, must be able to understand the study and comply with the study requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
Patients are excluded from the study if any of the following criteria are met:
1. Patients with predominant abdominal pain/discomfort in the opinion of the investigator
2. Presence of an obstructing structural lesion in the stomach or small intestine if observed during treatment gastrointestinal endoscopy (visit 2, randomization; week 0)
3. Patients taking drugs that interfere with the effect of botulinum toxin type A
4. Patients previously treated with intrapyloric injection of botulinum toxin type A;
5. Females who are pregnant or lactating
6. Patients with diabetes mellitus
7. Patients with delayed gastric emptying due to systemic disorders, e.g. systemic lupus erythematosus (SLE), sclerodermia, hypothyroidism
8. Patients with disorders of neuromuscular transmission, e.g. myasthenia gravis and Eaton-Lambert syndrome
9. Patients with abdominal surgery in their medical history, except (laparoscopic) appendectomy, (laparoscopic) cholecystectomy and/or hysterectomy
10. Patients with any condition which, in the opinion of the investigator, makes the patient unsuitable for entry into the study

Date of first enrolment
01/06/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
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2300 RC

Sponsor information

Organisation
Leiden University Medical Center (LUMC), Department of Gastroenterology and Hepatology (The Netherlands)

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Sponsor type
University/education

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
University/education

Funder Name
Leiden University Medical Center (LUMC) Department of Gastroenterology and Hepatology

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