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Pilot study to evaluate preliminary safety and efficacy of a novel gastric space occupying device as an aid for weight loss

Submission date	Recruitment status	[ ] Prospectively registered
28/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/03/2011	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
PTL-1000-0005-02

Study information

Scientific Title
A single centre 30-day observational non-randomised study to evaluate preliminary safety and efficacy of a novel gastric space occupying device as an aid for weight loss

Study objectives
The study is observational and no formal hypothesis testing will be conducted. The purpose is to evaluate the preliminary safety and effectiveness of the device as an aid to weight loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hospital Angeles in Tijuana, Baja California (Comité de Ética of Hospital Ángeles de Tijuana, Baja California), Mexico, approved on the 15th June 2010 (ref: PTL-1000-0005-02)

Study design
Single centre observational non-randomised unmasked study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Overweight, obese

Interventions
This will be an observational study where patients will serve as their own contol. No independent control group will be evaluated. Baseline weight, body mass index (BMI) and waist circumference will be obtained. Space occupying device will be administered and then weight, BMI, waist circumference will be obtained weekly for 4 weeks. At the end of 4 weeks, device will be removed. A last follow up visit/phone contact will occur one week after device removal.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Safety, characterised by the incidence of all adverse device effects (ADEs), possibly related to or related to the procedure and/or device, experienced by study participants. Adverse device effects are collected at a minimum weekly (day 7, 14, 21, and 28 +/- 2 days); however, they are documented at any time the patient notifies the study staff of a concern. There is no formal endpoint and the sample size does not support a formal endpoint to be evaluated.

Secondary outcome measures
Information on preliminary efficacy, obtained by measurements of total weight loss and excess weight loss during the 30 days of device use as compared to baseline

Overall study start date
12/01/2011

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Aged between 21 - 64 years, either sex
2. Body mass index (BMI) 27 - 40 kg/m2
3. No history of weight reduction of more than 5% of total body weight in the past 6 months
4. Must be able to comply with all study requirements for the duration of the study as outlined in the protocol. This includes complying with the visit schedule as well as study specific procedures such as: electrocardiography, endoscopy, upper gastrointestinal radiography, as well as clinical lab testing.
5. Must be able to understand and be willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Have unstable angina, myocardial infarction within the past year or heart disease classified within the New York Heart Association (NYHA) Class III or IV functional capacity
2. Be taking chronic aspirin or other non steroidal anti-inflammatory agents or other medications known to be gastric irritants, and unwillingness to discontinue the use of these concomitant medications: antiarrythmics, anti-anginal medications, anticoagulants or medications for

congestive heart failure
3. Be taking blood pressure medications, unless their blood pressure is controlled and they have been at stable dose for at least 3 months
4. Have type 1 diabetes or type 2 diabetes requiring oral medications or insulin
5. History or symptoms of thyroid disease which is not controlled by medication
6. Have severe renal, hepatic, pulmonary disease or cancer
7. Past history of gastrointestinal surgery (excluding uncomplicated appendectomy)
8. Have a history of adhesive peritonitis
9. History or symptoms of esophageal and/or gastric varices
10. Have history or congenital or acquired GI anomalies (e.g. atresias, stricture, and/or diverticula)
11. History or symptoms of inflammatory bowel disease, such as Crohn's disease
12. History of/signs and/or symptoms of duodenal or gastric ulcer
13. Have gastroporesis
14. Pregnant or breastfeeding or intention of becoming pregnant during the study (if female of childbearing potential)
15. Currently using pharmaceutical agents for weight loss

Date of first enrolment
12/01/2011

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Mexico

Study participating centre
Obesity Control Center
Tijuana
Mexico
22320

Sponsor information

Organisation
Obalon Therapeutics, Inc. (USA)

Sponsor details
5421 Avenida Encinas
Suite F
Carlsbad
United States of America
92008

Sponsor type
Industry

ROR
https://ror.org/03k4rxa78

Funder(s)

Funder type
Industry

Funder Name
Obalon Therapeutics, Inc. (USA)

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