# 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	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Ariel Ortiz

### Contact details

Obesity Control Center Avenida Leona Vicario No. 1510 Zona Rio Tijuana Mexico 22320

# Additional identifiers

## Protocol serial number

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

## Study type(s)

Quality of life

## 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(s)

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.

# Key secondary outcome(s))

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

## 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

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

## 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)

### **ROR**

https://ror.org/03k4rxa78

# Funder(s)

## Funder type

Industry

## **Funder Name**

Obalon Therapeutics, Inc. (USA)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type

**Details**