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A non-invasive swallowable device for weight loss and obesity-related comorbidities

Submission date
18/09/2013

Recruitment status
No longer recruiting

Registration date
14/10/2013

Overall study status
Completed

Last Edited
14/10/2013

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Use of intra-gastric balloons is common to treat obesity but these devices have limitations such as the need for endoscopy and anaesthesia. This study will assess the safety and efficacy (short and long term) of a new, really non-invasive, intra-gastric balloon called the Obalon Gastric Balloon (OGB).

Who can participate?
The study aims to recruit about 100 men and about 100 women that are overweight and obese patients, over 18 years old, in the Obesity Centre of Excellence of the Policlinico Umberto I General Hospital, Rome (Italy).

What does the study involve?
The OGB is a new balloon to be swallowed and then remotely inflated with 250cc nitrogen, without endoscopy or anaesthesia. Additional OGBs will be added according to weight loss and patients compliance. After the three-month treatment period, all balloons will be retrieved during an upper endoscopy, under no or conscious sedation.
Participants will swallow a capsule attached to a micro catheter; the balloon is inside the capsule. Once in the stomach, the balloon will be inflated with gas using the micro catheter; the micro catheter is then detached and removed, leaving the balloon behind.

What are the possible benefits and risks of participating?
Obalon is a non-surgical and fully reversible device with a strong safety profile (very low risk for the patient). It will provide a clinically meaningful weight loss. It is easy to repeat the Obalon therapy as needed. It is affordable.
Risks: not specified at time of registration

Where is the study run from?
The study has been set up by the Sapienza University of Rome (Italy) and is run from the Obesity Centre of Excellence of the Policlinico Umberto I General Hospital, Rome (Italy).

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start mid-2013. Participants will be enrolled on the study

for a period of two years. However, the study will extend beyond this as we intend to look at participants health over many years to evaluate the weight and obesity comorbidities.

Who is funding the study?
No external funding will be provided for this study. The costs of the devices will be covered by the Italian National Health System, as part of the normal obesity management.

Who is the main contact?
Prof. Alfredo Genco
alfredo.genco@uniroma1.it

Contact information

Type(s)
Scientific

Contact name
Prof Alfredo Genco

Contact details
Surgical Sciences Department
Viale del Policlinico 155
Rome
Italy
00161

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Study on a non-invasive swallowable device for weight loss and obesity-related comorbidities in overweight and obese patients

Study objectives
A minimally invasive swallowable intragastric balloon could be better for patients than other available devices in terms of placement discomfort (the device do not require endoscopy to be placed) and post-placement symptoms. In the meantime, it should be effective as the other commercially available intragastric balloons in short and long term (on weight and comorbidities) and safe (adverse events).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study is under evaluation of the internal general hospital ethical committee.

Study design
Single center, interventional clinical trial (single arm)

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Obesity, overweight

Interventions
A new intragastric balloon, Obalon® Gastric Balloons (OGB) (ObalonTherapeutics, Inc., Carlsbad, San Diego, California) will be inserted. Obalon is a gas-filled balloon with a maximal volume of 250 ml. It is compressed, folded, and fitted in a gelatin capsule. The balloon contains a self-sealing valve connected to a thin catheter. The Obalon is a non-surgical and fully reversible device with a strong safety profile (very low risk for the patient). It will provide a clinically meaningful weight loss. It is easy to repeat the 'Obalon therapy' as needed.
The OGB is swallowed and then remotely inflated with nitrogen 250cc, without endoscopy and /or anesthesia. Once the capsule is ingested, the catheter extends from the stomach to outside the body through the esophagus and the mouth. Fluoroscopy is used to verify that the capsule has entered the stomach. The catheter is attached to the balloon for remote inflation using a gas-filled canister. After balloon inflation, the catheter is detached and removed. Additional OGB balloons are added according to weight loss progression, patient symptoms, compliance to diet and perception of early satiety. After the three-month treatment period, all balloons will be retrieved during an upper endoscopy, under conscious sedation, using standard, commercially available endoscopic tools.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Weight loss parameters: Body Mass Index (BMI), Excess Weight Loss (EWL) percentage, weight loss (WL percentage. They will be evaluated at baseline, three months and follow-up.

Secondary outcome measures
1. Pain and post placement discomfort, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) at baseline, three months and follow-up
2. Changes in comorbidities - diabetes type 2 : measured by fasting glycemia, Hb1ac
3. Changes in comorbidities - hypertension: measured by changes in pharmacological therapy, systolic and diastolic pressure
4. Changes in comorbidities - obstructive sleep apnea syndrome (OSAS): measured by changes in pharmacological therapy (if present), apnea/hypopnea index and oxygen saturation, changes in oxygen therapy (C-PAP) if present

Overall study start date
01/06/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Obese (BMI > 30) and overweight (BMI > 27) patients
2. Both male and female
3. Aged over 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Anatomical abnormalities of the upper gastrointestinal (GI) tract
2. Functional disorders of the upper GI tract
3. Inflammatory and other pathophysiological conditions of the GI tract
4. Chronic or acute use of medications known to affect integrity of the GI tract and/or weight
5. Prior GI tract surgeries excluding uncomplicated appendectomies
6. Untreated hypothyroidism or untreated Cushings disease or syndrome
7. Severe, unstable/uncontrolled medical conditions of major organ systems

8. Alcohol and/or illicit drugs abuse
9. Undergoing chronic steroid or immunosuppressive therapy
10. Pregnant or breastfeeding or intention of becoming pregnant during the study
11. Have type 1 diabetes mellitus
12. Must not undertake scuba diving or travel in an unpressurized airplane cabin
13. Known allergies to products/foods of porcine origin
14. Untreated Heliocobacter pylori infection

Date of first enrolment
01/06/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Italy

Study participating centre
Surgical Sciences Department
Rome
Italy
00161

Sponsor information

Organisation
University of Rome - La Sapienza (Italy)

Sponsor details
Piazzale Aldo Moro 5
Rome
Italy
00185

Sponsor type
University/education

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
Government

Funder Name
The Italian National Health Service (INHS) (Italy) - as part of the normal obesity management

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