Feasibility study to evaluate the safety of PlenSat Digestible Balloons

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21950

Source
Nationaal Trial Register

Brief title
PlenSat2

Health condition

Obesity

Sponsors and support

Primary sponsor: PlenSat
Source(s) of monetary or material Support: Plensat bv.

Intervention

Outcome measures

Primary outcome

Main study endpoint is the time of survival of the PlenSat digestible balloon inside the human stomach, measured in weeks.

Secondary outcome

Not applicable.

Study description

Background summary

Obesity and obesity-associated comorbidities remain a major threat for Western populations. Throughout the past decades, several different treatments modalities have been established: lifestyle interventions and/or pharmaceutical approaches for overweight patients (BMI 25-29.9 kg/m2) and surgical interventions for the severe obese (BMI ≥40 kg/m2 or 35 kg/m2 in the presence of comorbidity). Patients suffering from class I obesity (BMI 30-34.9 kg/m2) or class II (BMI ≥35 kg/m2 without presence of comorbidity) are rarely considered for surgery and often fail to maintain weight losses accomplished by lifestyle interventions. For this specific patient population, there is a need for a safe and more effective therapy. It is hypothesised that intragastric balloons can provide a surrogate stomach fill, inducing an increase of satiety sensation and therefore a decrease in food intake.

Objective: The objective of this study is to evaluate the safety of the PlenSat Digestible Balloons.

Study design: This is a single-centre feasibility study to test the safety of digestible balloons in the treatment of adults with obesity. Subjects providing informed consent and meeting all study eligibility criteria will be enrolled in this prospective study. Baseline assessments for study eligibility will occur within 30 days prior to the procedure. Subjects will digest a single capsule, which will swell to a digestible balloon after encountering the acidic gastric environment. After approximately three weeks the balloon will be “naturally” digested by the gastrointestinal system. Study visits will be carried out weekly during the entire duration of the study until the balloon is fully digested and secreted in the faeces.

Study population: 3 male and 3 female volunteers, aged 18 – 80 years, will be enrolled and treated.

Intervention: The subjects enrolled in the study will ingest a single capsule under supervision of the medical team of investigators. The balloon will contain a radio-opaque tracer visible on X-ray. Weekly X-rays will be performed to monitor balloon location and evaluate final digestion and secretion of the balloon. Six patients will be included and treated sequentially, using a 1-1-2-2 inclusion algorithm. Patients will be enrolled after there is no radiographic evidence of a balloon in the gastrointestinal tract in patients of the previous block.

Main study parameters/endpoints: Duration of survival of the balloon inside the stomach is the main outcome of this study. Furthermore, a safety analysis will assess the occurrence of adverse events (AEs), serious adverse device effects (SADEs) and serious adverse events (SAE), monitored from the moment of ingestion of the capsule up to two weeks after observed digestion. Self-reported scores on symptoms of reflux and dyspepsia will complement the safety analysis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Each subject will swallow one single capsule. Per weekly site visit, each subject will undergo a short, general physical examination and will be asked to fill out the Gastrointestinal Symptom Rating Scale (GSRS). In addition, an X-ray of the abdomen will be carried out every weekly visit until the device is eliminated from the body. It is expected that each subject will visit the site 3 to 4 times after ingestion until the balloon is fully digested and the materials have left the body.

Study objective

It is hypothesised that intragastric balloons can provide a surrogate stomach fill, inducing an increase of satiety sensation and therefore a decrease in food intake.

Study design

From day 0, the patient’s physical status will be evaluated on a weekly basis.

Intervention

The subjects enrolled in the study will ingest a single capsule under supervision of the medical team of investigators. The balloon will contain a radio-opaque tracer visible on X-ray. Weekly X-rays will be performed to monitor balloon location and evaluate final digestion and secretion of the balloon. Six patients will be included and treated sequentially, using a 1-1-2-2 inclusion algorithm. Patients will be enrolled after there is no radiographic evidence of a balloon in the gastrointestinal tract in patients of the previous block.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Subject, male or female, is age 18 to 80 years of age.
2. Subject must be able to understand and be willing to sign an informed consent document.
3. Subject must be willing and able to participate in all aspects of the study and agree to comply with all study requirements for the duration of the study. This includes availability of reliable transportation and sufficient time to attend all follow-up visits.
4. Subject has a BMI of 30 – 39.9 kg/m2.
5. Subject must be of sufficient and stable medical health, as evaluated by the Principal Investigator.
6. Subject must have a primary care physician that will manage the subject for any comorbid conditions throughout the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. The subject has a history of gastro-duodenal ulcer disease and/or signs and/or symptoms of gastro-duodenal ulcer disease, which are treated with proton pump inhibitors (PPIs).
2. Subject has poorly controlled diabetes as indicated by the lack of stable diabetes medications and doses over the last month, or has a history of diabetes for greater than 10 years.
3. Subject has significant oesophageal disease including Zenker’s diverticulum, grade 3-4 reflux esophagitis, stricture, Barrett’s oesophagus, oesophageal cancer, oesophageal diverticulum, dysphagia, or achalasia.
4. Subject has significant signs of dysmotility of the gastrointestinal tract and/or uses prokinetic drugs/agents (domperidone, erythromycin, metoclopramide, etc.) or laxative drugs (macrogol, lactulose, etc.).
5. Subject uses opioid drugs and/or medications (codeine, tramadol, fentanyl, morfine,etc.) for any disease or symptoms, or has used opioid drugs/medications during the past six weeks.
6. Female subject is pregnant (diagnosed with a positive urine or blood pregnancy test prior to the procedure), is suspected to be pregnant, is lactating or is of childbearing potential but refuses to use adequate contraception during the study.
7. Subject has had previous bariatric, gastric or oesophageal surgery; intestinal obstruction; portal gastropathy; gastrointestinal tumors; oesophageal or gastric varices, or gastroparesis.
8. Subjects who have current or potential neck masses and/or swallowing disorders that, in the opinion of the investigator, may cause swallowing problems during the procedure.
9. Subject currently uses or has a history of illicit drug(s) use, or abuses alcohol (defined as regular or daily consumption of more than four alcoholic drinks per day).
10. Subject has participated in a clinical study with an investigational new drug, biological, or therapeutic device within £ 28 days prior to the enrolment in this study, and does not agree

to abstain from participation in other clinical trials of any kind during this study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2020
Enrollment:	6
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	20-02-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8434
Other	METC azM/UM : METC19063

Study results