PlenSat Study

No registrations found.

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

Summary

ID

NL-OMON22176

Source
NTR

Brief title
PlenSat study

Health condition

Obesity, Obesitas

Sponsors and support

Primary sponsor: Performer: Maastricht University Medical Center
Sponsor: PlenSat B.V.
Source(s) of monetary or material Support: PlenSat B.V.

Intervention

Outcome measures

Primary outcome

Survival time of balloon inside subject's stomach

Secondary outcome

Safety analysis: adverse events, serious adverse device effects and serious adverse events

Study description

Background summary

This is a single-centre first-in-human feasibility study, performed in the Netherlands, to test the safety of PlenSat Intragastric Balloons (IGBs) in the treatment of adults with obesity.

The PlenSat IGBs are pH-sensitive plant-based devices that are ingested orally, after which they are supposed to swell in the stomach to an end volume of 30 ml, thereby inducing satiety. They are designed to remain in the stomach for approximately four weeks, after which they burst and are excreted with the feces. Ultimately, approximately 10 IGB-containing capsules should be ingested for sufficient volume occupation. The subjects enrolled in the study will ingest a single capsule.

Capsule ingestion will occur 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.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.

Patients are included sequentially on a 1-1-2-2-2 basis. After the balloon of the first patient is excreted, a safety evaluation will occur, after which the second patient is included.

Study objective

The gastric balloons are expected to remain in the stomach for approximately four weeks, after which they burst and are fecally excreted. It is further 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

Weekly evaluation

Intervention

One (1) PlenSat Intragastric Balloon

Contacts

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Eligibility criteria

Inclusion 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 co-morbid conditions throughout the study.

Exclusion criteria

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:	Suspended
Start date (anticipated):	27-08-2018
Enrollment:	8
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-08-2018
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	NL7245
NTR-old	NTR7444
Other	Clinical Trial Centre Maastricht : PE-02480

Study results

Summary results
N.a.