PlenSat Study

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Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22176

Bron
Nationaal Trial Register

Verkorte titel
PlenSat study

Aandoening

Obesity, Obesitas

Ondersteuning

Primaire sponsor: Performer: Maastricht University Medical Center
Sponsor: PlenSat B.V.
Overige ondersteuning: PlenSat B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Survival time of balloon inside subject's stomach

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Weekly evaluation

Onderzoeksproduct en/of interventie

One (1) PlenSat Intragastric Balloon

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	27-08-2018
Aantal proefpersonen:	8
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7245
NTR-old	NTR7444
Ander register	Clinical Trial Centre Maastricht : PE-02480

Resultaten

Samenvatting resultaten
N.a.