Single center, prospective, single-arm feasibility study to evaluate the safety of the PlenSat Digestible Balloons in the treatment of Obesity

Published: 03-05-2018
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The objective of this study is to evaluate the safety of the PlenSat Digestible Balloons.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON46714

Source
ToetsingOnline

Brief title
Safety of PlenSat Digestible Balloons in Humans

Condition

- Appetite and general nutritional disorders

Synonym
Obesity, severe overweight

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: PlenSat inc.

Intervention

Keyword: Intragastric balloon, Obesity, Safety

Outcome measures

Primary outcome

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.

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.

Study 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 inflate 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.

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.

Study burden and risks

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.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6229HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6229HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18-80 years of age
Able and willing to sign an informed consent document
BMI of 30-39.9 kg/m^2
Sufficient and stable medical health
Must have a primary care physician

Exclusion criteria

Signs/symptoms of gastroduodenal ulcer disease (in history or present)
Poorly controlled diabetes or diabetes >10yr
Signs/symptoms of oesophageal or gastric disease (in history or present)
Signs/symptoms of dysmotility of gastrointestinal tract
Use of opioid drugs (past six weeks or present)
Female subject is pregnant or suspected to be pregnant, or lactating
Previous bariatric, gastric or oesophageal surgery
Swallowing disorders
Illicit drug use or alcohol abuse
Participation in other clinical study within past 4 weeks

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2018
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	PlenSat Digestible Balloons
Registration:	No

Ethics review

Approved WMO Date:	03-05-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-10-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL63462.068.17