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Investigating the effect and safety of the Satisphere™ insert in overweight patients

Submission date	Recruitment status	[ ] Prospectively registered
11/09/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/10/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/02/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The SatiSphere is a new device for the treatment of obesity. It is implanted into the stomach and duodenum (the first part of the small intestine) through an endoscope (a long, thin, flexible tube) under general anaesthetic. It is designed to help reduce food intake by slowing the passage of food through the duodenum, tricking the body into sensing more food intake than has occurred. The aim of this study is to provide information about the feasibility, short-term effectiveness, and safety of the SatiSphere device.

Who can participate?
Overweight people (BMI between 30 and 50), aged 18-60

What does the study involve?
Participants are randomly allocated to one of two groups. One group are implanted with the SatiSphere, and the other group are treated with diet and exercise only. The effectiveness of the SatiSphere is assessed in terms of weight loss in the SatiSphere group compared to the diet and exercise group after 3 months. Safety is assessed as the number of serious device or procedure related adverse events (side effects) over the study period of 3 months. Patients are also asked for any positive or negative symptoms possibly related to the SatiSphere device at monthly intervals.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Universitätsklinikum Hamburg-Eppendorf (Germany)

When is the study starting and how long is it expected to run for?
October 2011 to December 2012

Who is funding the study?
Endosphere Inc (USA)

Who is the main contact?
Prof. Thomas Rösch
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ENDO 2009-003

Study information

Scientific Title
A multicenter study to investigate the efficacy and safety of the Satisphere™ duodenal insert in overweight patients

Study objectives
1. To determine weight-loss compared to a control group
2. To evaluate device safety

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburg Ethics Commission, 07/02/2010, ref: 09/2925

Study design
Open randomised trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
Endoscopic treatment with a new device (Satisphere)

Sixty patients will be enrolled in 2 sites, twenty of whom will be randomized to a diet-only control group.
Recruitment is expected to start in April 2010. The clinical phase of this study will take approximately 8 months.
The SatiSphere device is a self-anchoring, conformationally stabilized device. The device is endoscopically delivered, easily removable and is preformed to take the shape of the duodenum. The SatiSphere device is designed to self-anchor in humans by using the following features of the human anatomy:
1. The general C shape of the duodenum
2. The two fixed points of the duodenum in the first portion where the duodenum passes through the peritoneal wall, and in the fourth portion where the duodenum is immobilized by the ligament of Treitz..

The SatiSphere Device is designed to help reduce food intake by slowing the passage of food through the duodenum, tricking the body into sensing more caloric intake than has occurred. EndoSphere is focused on using the bodys endocrine system to signal satiety early, and to down-regulate liver glucose production.
Current evidence supports a role for gastrointestinal peptides as regulators of satiety.

Screening will consist of:
1. Anthropometric and clinical parameters: Body weight, height, BMI and physical exam,
2. Medical history: Complete medical history will include evaluation of past or present cardiovascular, respiratory, gastrointestinal, renal, hepatic, neurological, endocrine, lymphatic, hematological, immunological, dermatological, psychiatric, genitourinary, and surgical history or any other diseases or disorders.
Any currently active medication will be recorded.
3. Vital signs (Blood pressure and pulse rate: sitting after 3 minutes rest, and body temperature.
4. 12 lead ECG

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Excess weight loss (EWL) after 3 months of therapy

Key secondary outcome(s))
1. Proportion of overweight patients who achieve a 10% or greater excess weight loss (EWL) after 3 months of therapy
2. Total weight (kg) loss after 3 months of therapy
3. Frequency and severity of all (serious and non-serious) device/procedure related adverse

events over 3 months
4. Frequency and severity of all non-device/non-procedure related adverse events over 3 months
5. Tolerance of the SatiSphereTM Duodenal Insert, indicated by premature removal of the SatiSphere due to excess nausea or pain
6. Frequency of migration of the SatiSphereTM Duodenal Insert between 72 hours and 3 months post insertion
7. Effect on tissue health of the SatiSphereTM Duodenal Insert over a 3 month period

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Male and female aged 18-60 years
2. Men or non-pregnant women (only women who are post-menopausal, surgically sterile or practicing a reliable contraception such as:
2.1. Hormonal [oral] contraception
2.2. Intrauterine device
2.3. Condom
2.4. Diaphragm
3. BMIs between 30 and 50
4. Patients who are healthy as determined by pre-study medical history, physical examination, 12 lead-ECG
5. Patients who are able to understand the protocol
6. Patients who have been informed of the nature of the study and have agreed to its provisions and given written informed consent as approved by the Local Research Ethics Committee or the physician of the respective clinical site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Classified in anesthesia risk group, ASA Class 4-5
2. Crohns disease or Ulcerative Colitis (inflammatory bowel disease)

3. Endocrine or other disorders that can cause obesity
4. Pregnancy (a urinary test for pregnancy must be performed in female patients before inclusion in the study)
5. Women who may be attempting to become pregnant
6. Type 2 diabetes defined as fasting plasma glucose (FPG) level of >126 mg/dL and a HbA1c level > 6.5% (or at least 1 percent above the reference laboratory's upper range of normal). NB: the presence of hyperlipidemia (hypercholesterolemia, hypertrigyliceridemia) is not an exclusion criterion)
7. Present alcohol or drug abuse or a smoker
8. Previous bariatric (including lap-band) or gastrointestinal surgery
9. History of bleeding diathesis or coagulopathy or will refuse blood transfusions;
10. Patients at need of anticoagulation therapy, Aspirin, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), or steroids
11. Experienced a hematologically significant gastrointestinal (GI) bleed within the past six months
12. Has other medical illness (i.e., congestive heart failure) that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life-expectancy (i.e., less than one year)
13. Simultaneously participating in another device or drug study, or who has participated in any clinical trial involving an experimental device within 6 months or experimental drug or device within 30 days of study entry
14. Significant depression or borderline personality disorder as indicated by medical record and /or clinical interview
15. Active suicide ideation and/or History of multiple suicide attempts within the past 5 years
16. Active psychosis present (current evidence of active psychosis and/or mental health hospitalization for psychosis in past 1 year)
17. Patients known to be binge eaters or with other eating disorders

Date of first enrolment
01/10/2011

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Hamburg-Eppendorf
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20246

Sponsor information

Organisation
Endosphere Inc (USA)

ROR
https://ror.org/005f11v91

Funder(s)

Funder type
Industry

Funder Name
Endosphere Inc (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes