Open prospective study to evaluate the safety and preliminary effectiveness of the BaroSense ACE(TM) Stapler for plication of dilated post-surgical gastric anatomy

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Determine the safety and preliminary efficacy of the new ACE Stapler in the specific tissue apposition application of repairing dilated post-surgical gastric anatomy over a 12 month follow-up period.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35914

Source
ToetsingOnline

Brief title
Gastric Pouch Revisions with BaroSense Stapler

Condition

- Gastrointestinal therapeutic procedures

Synonym
gastric bypass requiring revision, Obesity

Research involving
Human

Sponsors and support

Primary sponsor: BaroSense Inc
Source(s) of monetary or material Support: BaroSense;Inc.

Intervention

Keyword: endoscopic stapler, Gastric Pouch Revision, obesity

Outcome measures

Primary outcome

Safety

All subjects for whom the dilated tissue procedure is initiated (defined as introduction of the ACE stapler and the attempt made, whether or not successful, to place a plication) will be included in the safety analysis.

Subjects for whom the dilated tissue procedure with the ACE Stapler was completed (defined as at least 1 plication formed) will be included in the intent to treat population.

The primary safety analysis will assess the occurrence of adverse events through 12 months following procedures. Included in this assessment will be the proportion of subjects with any of the following outcomes between enrollment and completion of the 12 month follow-up evaluation: Adverse Events (AE), Adverse Device Effects (ADE), Serious Adverse Events (SAE) and Unanticipated Adverse Device Effects (UADE).

Secondary outcome

Efficacy

Efficacy outcome measures (variables) will be analyzed relative to the surgery visit and include:

• Percent of plications still visible at the 12 month endoscopy

• Percent Excess Weight Loss (%EWL) defined as: (preop weight-current weight)/(preop weight - ideal weight) *100, where ideal weight is calculated from a BMI of 25 based on the subject*s height.

• Total weight lost (kg)

• Change in body mass index (BMI)

• Change in waist circumference

• Improvement in co-morbid disease(s) including, but not limited to, improvement in vital signs and/or laboratory values

• Improvement of dumping syndrome for subjects who have this complication post RYGB

• Improvement in quality of life as indicated by the SF-36 Quality of Life questionnaire evaluated relative to baseline

Study description

Background summary

Surgery for intentional weight loss consistently produces meaningful reductions in excess weight and resolution or improvements in weight related co-morbidities. However, 20-30% of patients regain weight and are again susceptible to the adverse effects of increased BMI. In a large portion of these patients, dilation of the gastric pouch, gastrojejunostomy or both, causes the weight regain.

Surgical revision is possible, but even in skilled hands these operations are difficult and carry increased complication rates over primary bypass procedures. Some surgeons have employed the adjustable band over a dilated pouch with some success. Newer trans-oral procedures seek to reduce the diameter of the dilated anastomosis, reduce the volume of the pouch or both.

The ACE stapler creates large serosa to serosa plications. This study seeks to

determine the safety and optimal use of this plicating system for patients with dilated pouch and/or stoma who have experienced weight regain some time after their initial RYGB (Roux en Y Gastric Bypass) procedure.

Study objective

Determine the safety and preliminary efficacy of the new ACE Stapler in the specific tissue apposition application of repairing dilated post-surgical gastric anatomy over a 12 month follow-up period.

Study design

Open prospective study to evaluate the safety and preliminary effectiveness of the BaroSense ACE Stapler for plication of dilated post-surgical gastric anatomy.

Up to 30 total subjects will be enrolled at 3 participating sites (up to 10 subjects per study site).

All enrolled subjects will undergo a single endoscopic procedure under general anesthesia, during which the ACE stapler will be used to create full thickness serosa to serosa tissue plications. All subjects will have periodic study visits during the study.

Intervention

The Subjects enrolled in the study will be administered sedation and general anesthesia consistent with standards and practices at the investigational site. The subject will then have an endoscopic evaluation of the esophagus and stomach pouch to rule out any conditions that might preclude inclusion into the study. An endoscope is used to visualize the target tissue and to place a guidewire. The stapler is introduced over the guidewire. A flexible endoscope passes through the stapler after the stapler has been introduced. The stapler head is then articulated to reach the desired target tissue. A vacuum source is applied to bring the wall of the stomach/esophagus within the chamber of the stapler head. Opening and closing the staple head is controlled by the surgeon using commercial inflation devices. The stapler head is then compressed, or closed, and the staples fired to create a plication. Each full thickness plication is formed by compressing two concentric rings of titanium staples and a plastic (PEEK) reinforcement ring to form a permanent serosa to serosa fold. This step is repeated until the number of desired plications (expected to be 2-3) are formed.

Study burden and risks

Anesthesia related adverse events can be expected with this study. To mitigate

anesthesia risks, pre-existing respiratory, cardiopulmonary or other unacceptable general health risks are exclusion criteria for the study.
Trans-oral procedures can cause a range of adverse effects from incidental pain or damage to the esophageal tissues. The entire tissue acquisition, compression and stapling procedure can be visualized by the endoscope. This ability ensures the user can determine if a plication is properly and safely positioned in the gastric tissues, and that it does not incorporate esophageal or other non-desired tissue. These risks are also mitigated by the atraumatic design features of the instrument components that come in contact with the tissues.
Esophageal injury is a known adverse event associated with instrument and overtube delivery during endoscopic procedures. To reduce the chance of tissue injury, an endoscope is used to deliver a guidewire and the stapler is delivered over the guidewire. No overtube, which would increase the diameter of the system, is required for safe introduction of the stapler.
The escape of air into the peritoneum and/or gastric perforation are also risks for endogastric procedures. In the event of a perforation during the current study, clinical interventions (typically laparoscopic) can be immediately performed as the operating physicians are intended to be skilled bariatric surgeons.
Infection or cross-contamination is a risk with any reusable medical device. BaroSense has incorporated many material and design considerations to make the Stapler Handle similar in construction to commercially available endoscopes. Cleaning and high-level disinfection methods were tested in GLP validations for these tools. Clear instructions are provided to the user with each device.
With any medical device there are also risks associated with mis-use of the devices. BaroSense has mitigated the mis-use scenarios by design, where possible. BaroSense has further mitigated mis-use risks by compiling a complete labeling system to be delivered with the device that includes package labels, package inserts, reprocessing instructions and a procedure manual. These materials are all emphasized during comprehensive hand-on training provided to each investigator to augment the labeling.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Subject, male or female, is age 18 to 60 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 must be > 2 years post RYGB surgery.
5.Subject must have documented records indicating an initial achievement of > 60% EWL (based on an ideal weight of 25 BMI) at some point after RYGB surgery.
6.Subject has a BMI at baseline of > 30 and < 50. (for this protocol)
7.At time of enrollment, subject must have regained at least 35% of the maximum weight lost following RYGB, and the weight regain must have occurred over a period of not less than 3 months from the point of maximum weight loss.
8.Subject must have a stoma diameter of at least 18 mm (at the site the jejunum attaches to the pouch).
9.Subject must be fully ambulatory, without chronic reliance on walking aids such as crutches, walkers or a wheelchair.
10.Subject can undergo general anesthesia, as evaluated by the Principal Investigator.
11.Subject must be of sufficient and stable medical health, as evaluated by the Principal Investigator.
12.Subject*s general practitioner will be informed about the subject*s participation in this study. 13.Subject agrees to refrain from any type of reconstructive surgery that may affect body weight such as mammoplasty or abdominal lipoplasty or liposuction, during the trial.
14.Subject agrees to follow the post procedure aftercare program.

Exclusion criteria

1.Subject has a severe eating disorder.
2.Investigator determines that there is another causal factor for the subject*s weight regain other than dilated gastric anatomy.
3.Subject has previously undergone an endoscopic or surgical repair of dilated pouch or stoma (including sclerotherapy treatments).
4.Subject had irreversible or life threatening complications following initial RYGB procedure (cardio or respiratory).
5.Subject has an ongoing severe complication from their initial RYGB procedure (recurrent ventral hernia, pain syndrome, etc.).
6.Subject has an intragastric fistula, anastomotic leak, or staple/suture line disruption.
7.Subject has history of/or signs and/or symptoms of gastro-duodenal ulcer disease.
8.Subject has symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease.
9.Subject has pre-existing respiratory disease such as chronic obstructive pulmonary disease (COPD), pneumonia or cancer.
10.Subject has significant esophageal disease including Zenker*s diverticulum, grade 3-4 reflux esophagitis, stricture, Barrett*s esophagus, esophageal cancer, esophageal diverticulum, dysphagia, achalasia, or symptoms of dysmotility.
11.Subject has renal and/or hepatic insufficiency.
12.Subject has thyroid disease which is not controlled with medication.
13.Subject has a history of intestinal strictures or adhesions.
14.Subject has systemic infection in the body at the time of procedure.
15.Female subject who is pregnant (i.e., has 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.
16.Female subject who started birth control pills less than 3 months before enrollment, or who plans to start taking birth control pills during the study
17.Subject has had previous esophageal surgery; intestinal obstruction; portal gastropathy; gastrointestinal tumors; esophageal or gastric varices, or gastroparesis.
18.Subject has severe coagulopathy (prothrombin time > 3 seconds over control or platelet count < 100,000) or is presently taking heparin, coumadin, warfarin, or other anticoagulants or other medications which impede coagulation or platelet aggregation.
19.Subject is observed at baseline EGD to have malignant or poor quality/friable tissue in areas where the plications are likely to be placed.
20.Subjects who are unable to discontinue use of aspirin and/or non-steroidal anti-inflammatory agents (NSAIDs) at least 14 days prior to a procedure and continuing for 14 days post-procedure.
21.Subjects undergoing chronic steroid therapy.
22.Subjects undergoing immunosuppressive therapy.
23.Subjects who cannot discontinue either prescription or over the counter weight loss medications for at least 30 days prior to the procedure as well as during the trial period.
24.Subjects who have cardiac pacemakers or other electronic implantable devices.
25.Subjects who have hiatal hernias greater than 2 cm.
26.Subjects who have current or potential neck masses that in the opinion of the investigator,

may interfere with study-related procedures, or who have a Mallampati (intubation) score greater than 3.
27.Subjects who have poorly controlled psychiatric disease including but not limited to manic-depressive disorder, schizophrenia, borderline personality disorder, depression or suicidal tendencies.
28.Subject has Crohn*s disease or Ulcerative Colitis
29.Subject has chronic/acute upper GI bleeding conditions
30.Subject tests positive for H. pylori at baseline, unless treated before the procedure date.
31.Subject currently uses or has a history of illicit drug(s) or abuses alcohol (defined as regular or daily consumption of more than 4 alcoholic drinks per day).
32.Subject has started medications within the last 3 months that are known to cause weight gain.
33.Subject has participated in a clinical study with an investigational new drug, biological, or therapeutic device within <28 days prior to enrollment 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

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	endoscopic stapler
Registration:	No

Ethics review

Approved WMO

Date:	10-08-2011
Application type:	First submission
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
ClinicalTrials.gov	NCT01388673
CCMO	NL36707.068.11