A Randomized Controlled Multicenter Study of an Incisionless Operating Platform for Primary Obesity vs. Diet-Exercise alone: The MILEPOST Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40379

Source
ToetsingOnline

Brief title
MILEPOST

Condition

- Gastrointestinal therapeutic procedures

Synonym
Obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: USGI Medical, Inc

Source(s) of monetary or material Support: USGI Medical

Intervention

Keyword: Bariatric surgery, Endoscopy, Gastric plication, Obesity

Outcome measures

Primary outcome

Primary efficacy hypotheses:

* Mean %TBWL in the Treatment group will be * 5 % higher than the Control group

at 12 months

* The proportion of subjects achieving * 5% total body weight loss at 12 months

will be >50% in Treatment group

Secondary outcome

Secondary efficacy hypotheses:

* The proportion of patients achieving improvement of quality of life at 12

months will be larger in the Treatment group than in the Control group

* There will be significant differences in both time to satiety and caloric

capacity in the Treatment group as compared to the Control group at all

time-points following the intervention

Study description

Background summary

Rationale for Study
Even with the current bariatric treatment options available today, it is clear that there is still a need for minimally invasive procedures that provide safe and effective long-term weight loss results without the risks of surgery and without the limitations of temporary implants. USGI Medical, in collaboration with experts in the field, has developed a new endoscopic procedure to provide

a safe and effective treatment option for patients with Class I or II Obesity.
The procedure involves the creation of pleats in the fundus and distal body of the stomach with the intent to reduce stomach capacity and produce early satiety. Patients have reported less hunger and cravings after the procedure along with less food capacity. Like all other bariatric interventions, however, it is expected practice that a strict diet regimen be prescribed for all patients after the procedure. A tailored after care programme, with a prescribed diet, are standard practice for all weight loss interventions, including all standard bariatric procedures.
Weight loss results have been very promising and procedure complications have been less than 1.5% to date.The POSE* procedure is not a temporary intervention such as a balloon or intestinal barrier. It does not require revisions or removal and it does not limit follow-on procedures in the event that obesity progresses and surgery is required in later years. The procedure may provide additional benefits over diet and exercise alone with the intent of establishing long-term weight loss and resultant improvement in patient co-morbidities.
Therefore, we are conducting a RCT to compare the long-term weight loss results of patients undergoing the POSE procedure plus diet and exercise with those following a diet and exercise regime only. The patients and the aftercare requirements will be identical in both groups, thereby permitting fair and accurate isolation of the treatment effect. This places the proposed feasibility study in-line with the latest thinking on the subject and provides the investigators an opportunity to make a meaningful contribution to the science of this area.

Study objective

The primary objective of this study is:
* To evaluate the safety and effectiveness of the g-Cath* EZ Delivery Catheter with Snowshoe Suture Anchors* gastric procedure as an weight loss intervention compared to diet and exercise only.
A key secondary objective of this study is:
* To pool the weight loss data from this study with outcome data from previous studies to assess an overall treatment effect.

Study design

This RCT is using a multicenter, randomized, open-label, parallel-group, controlled study design intended to evaluate the safety and effectiveness of treating patients with primary obesity using the g-Cath* EZ Delivery Catheter with Snowshoe Suture Anchors* gastric procedure plus diet and exercise compared to diet and exercise alone.
Subjects will be randomly assigned in a 3:1 ratio to the Treatment and Control groups. Block randomizations with a block size of 4 (3 Treatment and 1 Control), will be carried out separately at each site. Randomization

assignments will be generated by an independent statistician and assigned to each consecutive subject through an electronic data capture system.

Intervention

Gastric plication
Diet and excercise

Study burden and risks

Similar to regular bariatric surgery, with the exception of the surgical risks that are less because of the less invasive nature of this procedure.

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

* Age 20-60 years
* BMI of >30 and <40 with or without a co-morbid condition
* Patient has failed more conservative weight reduction alternatives such as supervised diet, exercise or behavior modification programs in the last year
* No significant weight change (+/- 5% of total body weight) in last 6 months
* American Society Anesthesiologists-PS score * 2 (Appendix III)
* Has not taken any prescription or over the counter weight loss medications for at least 6 months
* Subject agrees not to have any additional weight loss interventional procedures or liposuction for at least 30 months following study enrollment,
* Subject is willing to cooperate with post-operative dietary recommendations and assessment tests
* Signed informed consent

Exclusion criteria

* History of (or intra-operative evidence of) bariatric, gastric or esophageal surgery
* Esophageal stricture or other anatomy and/or condition that could preclude passage of endolumenal instruments
* Severe Gastro-esophageal reflux disease (GERD), defined as symptoms that cause subject severe discomfort, compromise performance of daily activities, and/or condition is not entirely controlled with prescription drug therapy
* Known hiatal hernia >3cm by history or as determined by UGI exam or endoscopy
* Pancreatic insufficiency/disease
* Active peptic ulcer
* Pregnancy or plans of pregnancy in the next 12 months
* Present Corticosteroid Use
* History of inflammatory disease of GI tract; coagulation disorders; hepatic insufficiency or cirrhosis
* History or present use of insulin or insulin derivatives for treatment of diabetes
* Type II Diabetes Mellitus (as defined by HgbA1c >6.5) for greater than 2 years at the time of enrollment
* Uncontrolled Type II DM (HgbA1c >7.0 at screening)
* Quit smoking within last 6 months at time of enrollment or plans to quit smoking in the next year
* Immunosuppression
* Portal hypertension and/or varices
* Active gastric ulcer disease
* Gastric outlet obstruction or stenosis
* Beck Depression Inventory (Short) Score *12 (see Appendix IV)
* Subject has a history of drug or alcohol abuse or actively abusing either as defined by Cage and DAST questionnaires or positive UA drug screen

* Severe disturbances in eating behavior (i.e. binge eating)
* Known presence of a significant depression, psychosis, or other mood or eating disorder
* Actively treated depression (except for stable treated depression for >1year and normal BDI and psych exam)
* Present or past history of psychosis or other mood or eating disorder
* Non-ambulatory or has significant impairment of mobility
* Known hormonal or genetic cause for obesity with the exception of treated hypothyroidism
* Participating in another clinical study
* Is a first degree relative of investigator, or support staff involved in the study
* Employed by investigator or institution involved in the study or relative of same
* Subject is not able to provide written informed consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-05-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Incisionless Operating Platform (IOP) and g-CathTM EZ Suture Anchor Delivery Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-03-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NCT01843231
CCMO	NL46567.096.13