ENDURE II: AN INVESTIGATIVE, PROSPECTIVE, NON-RANDOMIZED, MULTI-CENTER STUDY TO ASSESS THE SAFETY AND EFFECTIVENESS OF A NOVEL GASTRIC RESTRICTIVE DEVICE, CALLED THE RESHAPE VEST*, IN PEOPLE WHO ARE OBESE.

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To assess the safety and effectiveness of the LGV in treating obese subjects with a BMI of 35 kg/m2 to 55 kg/m2 who have failed one or more conservative weight-reduction alternative(s), such as supervised diet, exercise, and behavior modification...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON49408

Source
ToetsingOnline

Brief title
ENDURE II Study

Condition

- Appetite and general nutritional disorders

Synonym
Obesity, Severe overweight

Research involving
Human

Sponsors and support

Primary sponsor: ReShape Lifesciences
Source(s) of monetary or material Support: ReShape Lifesciences

Intervention

Keyword: Gastric reduction, Gastric Vest, Obesity, Weight reduction

Outcome measures

Primary outcome

The primary endpoints are:

- The primary efficacy endpoint is to demonstrate at least 30% excess weight loss (%EWL) at 12 months1

- The primary safety endpoint is to evaluate safety by device and procedure-related serious adverse events by 12 months

Secondary outcome

The secondary endpoints are:

- To evaluate safety by device and procedure-related serious adverse events by 24 months

- To demonstrate an efficacy objective of the maintenance of at least 30% EWL at 24 months

- To demonstrate at least 40% EWL for at least 40% of subjects compared to baseline at 24 months

- To demonstrate at least 50% EWL for at least 35% of subjects compared to baseline at 24 months

Additional observations include:

- Change in BMI from baseline at months 12 and 24

- Percentage of total weight loss (%TWL) from baseline at months 12 and 24

- Change in neck, arm, waist and hip circumference from baseline at months 1, 3, 6, 9, 12, 18, and 24, and to explant and 1 month post *explant follow up

- Length of hospital stay associated with implantation

- Procedure time defined from first incision to closure

- Change in blood pressure from baseline at months 1, 3, 6, 9, 12, 18, and 24

- Change in quality of life (QOL) (IWQOL-L, SF-12, TFEQ and WPAI:SHP) from baseline at months 6, 12, and 24

- Change in metabolic parameters, cholesterol, glucose, and glycated hemoglobin from baseline at months 6, 12, 18, and 24

- Change in bio-markers associated with Nonalcoholic steatohepatitis (NASH), APRI (AST, PLT), Fib-4 (APRI components plus age, ALT) and NFS (Fib-4 components plus Albumin BMI), from baseline at months 6, 12, 18 and 24.

Study description

Background summary

Obesity is defined as having a Body Mass Index (BMI) of 30 kg/m² or higher. Obesity has become one of the most significant health problems in the world. Worldwide obesity nearly triples between 1975 and 2016, and is predicted to continually increase in the future. In 2016, more than 1.9 billion adults were overweight; and of these over 650 million were obese.

Diet, exercise, and behavior modification program(s) provide non-surgical treatments for obesity; however, success rates of long-term weight loss maintenance with lifestyle changes are low, ranging from 4%-8%.

To date, mainly gastric bypass surgery and sleeve gastrectomy surgery are proven effective, long term treatment for obesity. However, less invasive interventions are being considered to explore other ways to provide treatment of obesity without the high risks associated with surgery. This will provide treatment options to meet the needs of the millions of individuals who cannot or are not willing to undergo surgical intervention.

Study objective

To assess the safety and effectiveness of the LGV in treating obese subjects with a BMI of 35 kg/m2 to 55 kg/m2 who have failed one or more conservative weight-reduction alternative(s), such as supervised diet, exercise, and behavior modification program(s).

Study design

Investigative, prospective, non-randomized, multi-center study to assess the safety and effectiveness of the LGV for a duration of 24 months.

Intervention

The Laparoscopic Gastric Vest (LGV), branded the ReShape Vest*, is a long-term, silastic, implantable system that is placed around the stomach to encompass the gastroesophageal junction to the Incisura Angularis.

The intervention is the implantation of the LGV.

Study burden and risks

Possible General Risks of Anesthesia and Weight Loss Surgeries:
- Abnormal Stools
- Acute Cholecystitis/Gallstones
- Adverse reaction to anesthesia
- Bleeding
- Blood clots
- Cardiac Arrhythmias
- Gastritis
- Death/Cardiac arrest
- Dehydration
- Esophagitis
- Excess gas (cramps, bloating, gassiness)
- Excessive or inadequate weight loss
- Gastroesophageal reflux (GERD)
- Fatigue
- Hernia (hiatal or other)
- Hypoglycemia

- Inflammation
- Indigestion
- Infection
- Injury to the stomach, liver, intestine or other organs due to surgery
- Leaks in the gastrointestinal system
- Loss of appetite
- Lung or breathing problems
- Malnutrition
- Nausea and vomiting
- Obstruction, bowel
- Obstruction, stomach
- Pain
- Pancreatitis
- Perforation
- Psychosocial and sexual malfunction
- Redundant Skin
- Ulceration

Possible Risks of Study Device and/or Procedure:
- Device Malfunction
- Dilation of the esophagus
- Dysphagia (difficulty swallowing)
- Erosion of the stomach or esophagus
- Proximal or distal pouch dilation
- Device slippage
- Suture failure
- Suture perforation
- Weight gain due to noncompliance of patient

Gastric Leaking:

Gastric leaking occurs when digestive juices and partially digested food leak into the cavity surrounding the stomach. Gastric leaking may be associated with the following signs and symptoms:
- Tachycardia (rapid heart rate)
- Oscillating heart rate
- Fever
- Hiccups
- Back left shoulder or epigastric pain (pain right below your ribs)
- Nausea
- Dyspnea (difficult or labored breathing) or shortness of breath
- Bloody saliva
- Elevated white blood cell count (potential sign of an infection)
- Shortness of breath

Device Failure:

The minimum tested lifetime of the Vest is 10 years. Should the device*s integrity and/or function deteriorate over time, the subject should discuss alternative treatment options with the study doctor. Options may include a revision surgery to remove the LGV.

Reoperation/Device Removal:

Decisions to remove the LGV may be required which could lead to adhesions, making the explantation of the device difficult and complicated. Rapid weight loss could result in complications that may require additional surgery or device removal.

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. Age * 22 and * 65 years * between 22 and 65 years of age;
2. Obesity class II and III (Body mass index (BMI) * 35 kg/m2 to 55 kg/m2); Subjects with a BMI * 35 to < 40 kg/m2 may be enrolled in the presence of at least one obesity-related comorbidity.
3. Failed one or more conservative weight-reduction alternative(s), such as supervised diet, exercise, and behavior modification program(s) within the last five years;
4. Able to comprehend, follow and give signed informed consent;
5. Reside within a reasonable distance from the Investigator's treating office and able and willing to travel to the Investigator's office to complete all routine follow-up visits;
6. Ability to comply with all study requirements for the duration of the study, as outlined in the protocol, willing to submit to significant lifestyle changes that include diet, eating and exercise habits for the duration of the clinical study;
7. Females of childbearing potential (FOCBP) must be willing to avoid pregnancy throughout the duration of the study, including follow-up, and must agree to the following:
o have a negative serum pregnancy test at screening,
o negative urine pregnancy test day of implant,
o and inform the investigator immediately if the subject becomes pregnant;
8. Willing to abstain from illegal drugs, including marijuana and tobacco (all forms) during study participation;
9. Willing to limit alcohol consumption following the opinion of the Science Group of the European Alcohol and Health Forum of the European Commission;
10. Have a stable concomitant medication regimen at the time of screening to mitigate drug induced weight fluctuations. A stable regimen is defined as 90 days without the introduction of or change in medication;
11. Agrees to refrain from any type of reconstructive surgery/procedures that would affect body weight (such as abdominal lipoplasty or liposuction, mammoplasty, removal of excess skin or cool sculpting) during the follow-up period after placement of the LGV

Exclusion criteria

1. Genetically-caused obesity, such as Prader-Willi syndrome; or any disease state know to affect weight status such as Cushing*s syndrome, untreated sleep apnea, inadequately treated thyroid disease;
2. History of chronic and/or ongoing clinically significant conditions or disorders of the gastrointestinal (GI) tract, i.e. Gastroparesis and

Inflammatory Bowel Diseases such as Ulcerative Colitis and Crohn*s disease;
3. Any abnormal stenosis or obstruction of the GI tract;
4. Significant acute and/or chronic active infection including H. pylori and urinary tract infection;
5. History, or signs and/or symptoms of acid-peptic disease (APD) or gastric or duodenal ulcer;
6. Diagnosis of portal hypertension, cirrhosis and esophageal varices;
7. Presence of renal or liver disease defined as estimated Glomerular Filtration Rate (eGFR) < 45 ml/min/1.73 m2, ALT or AST > 2x upper limit normal (ULN) or total bilirubin >1.5x ULN;
8. Previous stomach or bowel surgery;
9. Previous bariatric procedure or device including, but not limited to, intragastric balloons within the past twelve months, sleeve gastrectomy, endoluminal suturing and restrictive bands;
10. History of adhesive peritonitis;
11. Presence of a hiatal hernia greater than 3 cm;
12. History of bleeding disorders such as hemophilia;
13. Subjects who are unable to tolerate abstinence from blood thinners, such as warfarin, during the peri-operative period;
14. Anemia defined as either: Hemoglobin (Hb) value for females of <11.0 g/dl, for males <12.0 g/dl;
15. Abnormal blood cell indices deemed to be clinically significant;
16. Diabetes requiring insulin at baseline (Type 1 or uncontrolled Type 2 defined as an HbA1c >12%) or a significant likelihood of requiring insulin treatment in the following 24 months;
17. History or known allergies to silicone or similar materials;
18. Participation in other investigational study protocols. If a subject has recently completed participation in another drug or device study, the subject must have exited that study at least 90 days prior to being enrolled in this study. If a subject screen failed prior to receiving study intervention the subject may participate in the study;
19. Concomitant use of (or within 90 days of screening), or unwillingness to avoid any use of, weight loss medications, weight loss supplements, weight loss herbal preparations and/or participation in any non-studyrelated organized weight loss program (commercial or medical) at any time during the study;
20. Undergoing chronic steroid or immunosuppressive therapy, defined as use of any oral and/or injectable steroid of any dose within 90 days of screening;
21. Smoking cessation within two years of study entry;
22. Major upper GI abdominal surgery (other than appendectomy, cholecystectomy, c-section);
23. Significant traumatic injury to the abdomen within 90 days prior to enrollment;
24. Subjects or immediate family members (e.g., biological parents, children, grandparents) with a known diagnosis or pre-existing symptoms of autoimmune connective tissue disease such as systemic lupus erythematosus or scleroderma;
25. Current use of medications known to cause metabolic disturbances, such as the antipsychotic agents olanzapine, quetiapine, and type 2 diabetes medication

thiazolidinedione (TZD);
26. Chronic use of Non Steroid Anti-Inflammatory Drugs (NSAID) which is defined as daily use for greater than one month (low dose aspirin 81mg daily is acceptable);
27. History or presence of malignancy such as cancer within the last five years with the exception of successfully treated non-melanoma skin cancer;
28. Any condition that, in the opinion of the Investigator, would compromise the well-being of the subject or the study or prevent the subject from meeting or performing study requirements (e.g., chronic pancreatitis, serious organic disease which make them poor surgical candidates, chronic infection, severe cardiopulmonary disease).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Reshape Vest(TM)
Registration:	No

Ethics review

Approved WMO

Date:	28-02-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO Date:	16-01-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	26-03-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	23-11-2020
Application type:	Amendment
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	NCT03918564
CCMO	NL66592.096.18