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A Prospective, Randomized Multicenter Study to Evaluate the Safety and Efficacy of the ReShape Duo™ Intragastric Balloon System in Obese Subjects

This study is enrolling participants by invitation only.

Sponsor:
ReShape Medical, Inc.

Information provided by (Responsible Party):
ReShape Medical, Inc.

ClinicalTrials.gov Identifier:
NCT01673698

First received: August 15, 2012
Last updated: January 15, 2013
Last verified: January 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The REDUCE Pivotal Trial is a pivotal clinical study designed to develop valid scientific evidence regarding the safety and effectiveness of the ReShape Duo® as an adjunct to diet and exercise in the treatment of obese subjects with one or more obesity-related comorbid conditions.

Condition	Intervention
Obesity	Device: ReShape Duo balloon Other: Diet & exercise counseling

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Prospective, Randomized Multicenter Study to Evaluate the Safety and Efficacy of the ReShape Duo™ Intragastric Balloon System in Obese Subjects

Resource links provided by NLM:

MedlinePlus related topics: Exercise and Physical Fitness Obesity Weight Control

U.S. FDA Resources

Further study details as provided by ReShape Medical, Inc.:

Primary Outcome Measures:

- Difference in the mean percent excess weight loss (%EWL) between the Treatment and Control Groups [Designated as safety issue: No]

Secondary Outcome Measures:

- Proportion of weight loss maintained following device removal for each Treatment Group subject (i.e. calculated as the ratio of % EWL maintained following device removal to the % EWL achieved during device implant) [Designated as safety issue: No]

Other Outcome Measures:

- Proportion of Treatment group subjects who achieve ≥ 25% EWL [Designated as safety issue: No]

Estimated Enrollment: 330

Study Start Date: August 2012
Estimated Study Completion Date: February 2014
Estimated Primary Completion Date: August 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: ReShape Duo Balloon ReShape Duo Balloon + diet & exercise counseling	Device: ReShape Duo balloon Other: Diet & exercise counseling
Sham Comparator: Diet & exercise counseling Diet & exercise counseling	Other: Diet & exercise counseling

Eligibility

Ages Eligible for Study: 21 Years to 60 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion criteria:

- Patients 21 to 60 years of age
- BMI ≥ 30 kg/m2 and ≤ 40 kg/m2
- At least 5 years of obesity (with BMI ≥ 30)
- Stable weight, defined as a subject who has not gained or lost ≥ 5% of body weight in the 3 months preceding the screening assessment
- Failure to lose weight, within the 36 months preceding the screening date, after participation in either of the following:
  1. A medically or commercially supervised weight loss program involving regular counseling regarding both diet and exercise.
  2. Use of an FDA-approved diet drug
- The presence of one or more obesity-related comorbid conditions
- Willing and able to provide Informed Consent
- Willing and able to comply with study procedures and visit schedules as specified by the protocol
- If female, the patient must
  1. be postmenopausal for at least 1 year OR
  2. be surgically sterile, OR
  3. if of child bearing potential, must be practicing birth control, be willing to avoid pregnancy for the year of study participation, have a negative serum pregnancy test at screening, and a negative urine pregnancy test at baseline
- Residing 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.

Exclusion criteria:

- History of and/or ongoing clinically significant conditions or disorders of the gastrointestinal(GI)tract
- Clinically significant and uncontrolled/unstable hepatic, reproductive, gastrointestinal, renal, hematologic, pulmonary, neurologic, psychiatric, respiratory, endocrine, or cardiovascular system diseases
- Significant acute and/or chronic infections of any kind.
- Severe coagulopathy, hepatic insufficiency or cirrhosis
- Uncontrolled or severe asthma, or any asthma requiring or likely to require inhaled steroid therapy during the anticipated duration of trial participation
- Severe obstructive sleep apnea
- Incompletely controlled hypothyroidism or hyperthyroidism
- Severe systemic disease [consistent with an ASA (American Society of Anesthesia) Physical Status Classification Score of 3 or greater]
- Eating disorders, especially binge eating
- Inability to walk 200 yards without assistance
- Known allergies to any of the device materials or accessories, i.e. silicone, methylene blue, corn starch
- Active drug or alcohol addiction within 12 months of enrollment
- Insulin-dependent diabetes (either Type 1 or Type 2) or a significant likelihood of requiring insulin treatment in the following 12 months

- Depressive disorder with total Beck Depression Inventory (BDI) score > 16 points, and/or BDI affective subscale score > 7 points at screening
- Ongoing treatment, or anticipated need for such treatment, with anticoagulants, known gastric irritants such as ASA or NSAIDs or agents that can promote gastrointestinal bleeding, within 1 month prior to enrollment, or unwillingness to forego these medications during the study period
- Participation within 60 days of screening date in previous or ongoing clinical trial or current usage of an investigational drug or device
- Any use of an intragastric device prior to this study.
- Genetically caused obesity, such as Prader-Willi syndrome
- Any prior bariatric surgery or likely to undergo bariatric surgery during study follow-up period
- Concomitant use of, or unwillingness to avoid any use of, weight loss medications, weight loss supplements, weight loss herbal preparations and/or participation in any non-study-related organized weight loss program (commercial or medical) at any time during the study, including online or smart phone applications to track or modify food intake, exercise regimens or weight
- Chronic opiate use (> 3 months continuous use) or likely need for opiate use during study participation
- Contraindication or allergy to, or unwillingness to use, proton pump inhibitor medication throughout study follow-up duration-Pregnancy, breast feeding, or intention of becoming pregnant during the study
- Any screening laboratory values outside of the normal range deemed clinically significant by the Investigator
- Anemia defined as either:
    1. Hemoglobin (Hgb) value for females of < 11.0 g/dl, for males < 12.0 g/dl
    2. Abnormal red cell indices and iron deficiency
- Smoking cessation within 3 months of study entry or plans to quit smoking during the study
- Major surgery, open biopsy or significant traumatic injury within 3 months prior to enrollment.
- History of significant adverse experience with sedation or anesthesia
- Serious or uncontrolled psychiatric illness or disorder that could compromise patient understanding of or compliance with study procedures
- Any condition that, in the opinion of the Investigator, would compromise the well-being of the patient or the study or prevent the patient from meeting or performing study requirements, including:
    1. Inability or unwillingness to sign the patient informed consent document.
    2. Inability to participate in all necessary study activities due to physical or mental limitations.
    3. Inability or unwillingness to return for all required follow-up visits.
- Employees/family members of ReShape Medical® or any of its affiliates or contractors
- Employees/family members of the Investigator, sub-Investigators, or their medical office or practice, or surgical, bariatric or hospital organizations at which study procedures may be performed
- An immediate family member (by marriage or blood relationship) of another subject already enrolled in the REDUCE Pivotal Trial

Endoscopic exclusion criteria:

- Peptic ulcerations
- Clinically significant hiatal hernia (> 3 cm)
- Patulous pyloric channel
- Erosive esophagitis
- Varices
- Angiectasias
- Barrett's esophagus
- Esophageal stricture
- Gastric mass
- Any other subject characteristic that would prevent the successful insertion of a ReShape Duo™ or that in the opinion of the Investigator preclude safe use of the ReShape Duo™

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01673698

Locations

United States, Arizona

Scottsdale Healthcare

Scottsdale, Arizona, United States, 85258

United States, Georgia

Hamilton Medical Center
Dalton, Georgia, United States, 30720

United States, Michigan

Marquette General Surgical Weight Loss Center
Marquette, Michigan, United States, 49855

United States, Minnesota

University of Minnesota/Department of Gastrointestinal Surgery
Minneapolis, Minnesota, United States, 55455

United States, Missouri

Washington University in St. Louis
St. Louis, Missouri, United States, 63110

United States, South Carolina

Greenville Hospital System
Simpsonville, South Carolina, United States, 29680

United States, Tennessee

Midsouth Bariatrics
Memphis, Tennessee, United States, 38120

United States, Texas

University of TX Health Science Center at Houston
Houston, Texas, United States, 77030

Sponsors and Collaborators

ReShape Medical, Inc.

Investigators

Study Director:	John Lehmann, MD, MPH	Lehmann Consulting
Principal Investigator:	Jaime Ponce, MD	Hamilton Medical Center

More Information

No publications provided

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ClinicalTrials.gov Identifier:	NCT01673698 History of Changes
Other Study ID Numbers:	The REDUCE Pivotal Trial
Study First Received:	August 15, 2012
Last Updated:	January 15, 2013
Health Authority:	United States: Food and Drug Administration

Keywords provided by ReShape Medical, Inc.:
obesity
weight loss

Additional relevant MeSH terms:

Obesity	Overweight
Overnutrition	Body Weight
Nutrition Disorders	Signs and Symptoms

ClinicalTrials.gov processed this record on February 03, 2013