

Mechanistic and Clinical Outcomes of a Surgical Innovation Aimed at Minimizing GERD Associated With VSG (INNOVATE-VSG)

NCT06783751

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of California, Irvine
Enrollment	44 participants

Key Eligibility Criteria

Inclusion (7)

- Male and female subjects aged 18-65 years
- Body mass index (BMI) 35-55 kg/m²
- Must meet the BMI criteria before and after 6 months of nonsurgical weight management
- Presence of GERD defined for this trial as acid exposure time (AET) of 4.9% or above as assessed with the Bravo pH test.
- Have health insurance which pays for the costs of bariatric surgery and standard medical care before and after surgery
- ... and 2 more (see full listing online)

Exclusion (20)

- Hiatal hernia >2cm (defined as maximum axial height from end of the esophagus to diaphragm by any study including upper endoscopy esophagram and or at the time of surgery)
- Evidence of clinically significant major esophageal motility disorder as determined by the site primary investigator
- Severe gastroparesis
- Previous bariatric or anti-reflux procedure
- Barrett's esophagus
- ... and 15 more (see full listing online)

Locations (2 total)

University of California, Irvine, Orange, California, United States
University of California, San Diego, San Diego, California, United States