

Apollo Endosurgery completes patient enrollment for MERIT

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Apollo Endosurgery, a leader in less invasive medical devices for gastrointestinal and bariatric procedures, has announced that the final patient has been enrolled in the Multi-Center ESG Randomized Interventional Trial (MERIT). The US-based, prospective randomized multi-centre-controlled trial is evaluating the effectiveness of the endoscopic sleeve gastroplasty procedure.

ESG is an endoscopic minimally invasive weight loss procedure based on full-thickness endoscopic suturing using Apollo's OverStitch device. In the ESG procedure, a series of sutures are placed through the gastric wall reducing the stomach volume by up to 80% creating a restrictive endoscopic sleeve. The result allows a patient to consume less food and remain satiated longer.

The purpose of the study is to demonstrate weight loss and quality of life at 12 months following the ESG procedure when compared to lifestyle modifications alone. Additionally, improvement in hypertension and type 2 diabetes at 24 months versus control will be measured. The MERIT-Trial is being conducted at nine sites in the United States. The trial's safety and effectiveness endpoints are based on endpoints set forth in a consensus statement of the American Society of Gastrointestinal Endoscopy (ASGE) and the American Society of Metabolic Bariatric Surgery (ASMBS) and its impact on obesity related co-morbidities in patients with obesity and body mass index (BMI) between 30 - 45 kg/m².

The trial enrolled two hundred patients (80 treatment / 120 control), stratified into three groups (Obesity, Obesity with hypertension, Obesity with diabetes). ESG participants who do not achieve the endpoints will receive a repeat upper endoscopy at 52 weeks +/- 4 weeks to evaluate stitch placement and thereafter remain in follow-up for twelve additional months. Control participants will follow a low-calorie, healthy lifestyle intervention for twelve months and then may be eligible for crossover to receive the ESG procedure.