

Non-Surgical investigational weight-loss surgery study underway

HonorHealth Research Institute is enrolling patients in the ENDObesity[®] II Trial

SCOTTSDALE, Ariz. (Nov. 10, 2015) – HonorHealth is the only site in Arizona participating in the ENDObesity II study, an FDA-approved clinical study to determine the safety and effectiveness of an incision-free, endoscopic weight loss procedure using the TransPyloric Shuttle[®] (TPS[®]).

Individuals with a body mass index (BMI) of between 30 and 40 may be eligible for the trial. The incision-free TPS outpatient procedure is performed entirely through the mouth without any incisions through the abdomen.

Physicians participating in the study using a thin flexible sheath that is passed through the mouth and into the stomach. Once placed, the TPS works with the stomach's natural digestion process to open and close the outflow valve of the stomach during digestion, helping to slow down the passage of food. The TPS remains in the stomach for up to 12 months.

"This new investigational approach – which is much less invasive than bariatric surgery and performed entirely through the patient's mouth – may help patients feel full sooner during meals, improving their feelings of fullness and reducing hunger cravings so they can control their portions, consume fewer calories and lose weight," said HonorHealth bariatric surgeon and principal investigator, Jim Swain, MD.

The ENDObesity II Trial is among the largest multicenter studies ever undertaken of an endoscopic approach to primary bariatric surgery, where patients are randomly assigned to one of two groups – the Treatment Group (two in three chance) or the Control Group (one in three chance). The Treatment Group will undergo the TPS procedure during their endoscopy and the Control Group will not. Both groups will receive the same diet and exercise counseling.

Even though surgery has been proven to be very effective for patients with a BMI greater than 35, fewer than two percent of eligible patients choose it as an option. "The TPS procedure is designed for patients that have a lower BMI but still struggle with their weight and are not eligible for traditional weight loss surgery," said Dr. Swain. "Nearly 60 million Americans fall into this category, and it is our hope as clinicians to provide options for these patients."

The American Heart Association (AHA) estimates that 78.4 million Americans age 20 and over are obese (with a BMI of 30.0 kg/m2 and higher). If current trends in the growth of obesity continue, total healthcare costs attributable to obesity could reach \$861 to \$957 billion by 2030, which would account for 16 percent to 18 percent of U.S. health expenditures, the AHA predicts.

To learn more about eligibility to enroll in the study or for additional information, visit <u>www.endobesitystudy.com</u> or call the HonorHealth Research Institute at 480-323-1292.

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About HonorHealth:

HonorHealth is a non-profit health system serving an area of 1.6 million people in the greater Phoenix, Arizona area. The network encompasses five acute care hospitals, an extensive medical group, outpatient surgery centers, a cancer center, clinical research, medical education, two foundations and community services with approximately 10,500 employees, 3,700 affiliated physicians and 3,100 volunteers. HonorHealth was formed by a merger between Scottsdale Healthcare and John C. Lincoln Health Network. HonorHealth's mission is to improve the health and well-being of those we serve. Learn more at HonorHealth.com.

Media Contact:

Alice Giedraitis HonorHealth Media Relations Manager 480-323-1950 <u>alice.giedraiits@honorhealth.com</u>