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NEWS RELEASE

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Bariatric Surgery or Medication/Lifestyle Modifications: Which has Better Long-term Effect on Type 2 Diabetes? Cleveland Clinic-Led Multicenter Trial to Assess Approaches
\$10.2 Million NIH Grant to Support First Long-Term Study

July 7, 2017, Cleveland: A team of [Cleveland Clinic](#) researchers is leading a first-of-its-kind multicenter clinical trial to assess the long-term outcomes of bariatric/metabolic surgery compared to medical and lifestyle therapy for treating Type 2 diabetes.

The Alliance of Randomized Trials of Medicine versus Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) consortium members are Cleveland Clinic, Joslin Diabetes Center/Brigham & Women's Hospital Boston, University of Pittsburgh and University of Washington. Each group completed previous studies that evaluated the short-term effectiveness of bariatric surgery compared to medical and lifestyle management on Type 2 diabetes and body weight.

With the support of a \$10.2 million National Institutes of Health (NIH) grant, the research team will merge study participants, procedures and outcome metrics. A total of 302 patients with Type 2 diabetes and mild to moderate obesity will be re-enrolled into ARMMS-T2D.

“The primary goal of the ARMMS-T2D clinical trial is to evaluate the effectiveness of bariatric surgery compared to medical therapy to treat Type 2 diabetes over a longer period of time. We will also identify clinical predictors of diabetes remission and relapse,” said [John Kirwan, Ph.D.](#), principal investigator and director of the [Metabolic Translational Research Center](#) at Cleveland Clinic Lerner Research Institute.

“ARMMS-T2D will provide the largest body of evidence to inform decision-making regarding long-term outcomes of bariatric/metabolic surgery compared to medical and lifestyle management of Type 2 diabetes,” added [Philip Schauer, M.D.](#), co-principal investigator and director of [Cleveland Clinic’s Bariatric & Metabolic Institute](#).

ARMMS-T2D is a follow-up study from four smaller-scale, randomized controlled trials conducted at the four consortium institutions, including the groundbreaking Cleveland Clinic-based [STAMPEDE](#) study, which demonstrated the short- and medium-term safety and efficacy of bariatric/metabolic surgery for Type 2 diabetes. Dr. Schauer is principal investigator of STAMPEDE and published results in [New England Journal of Medicine](#) demonstrating superior efficacy of surgery compared to medical treatment of Type 2 diabetes at five years follow up.

However, to date there are no multi-center trials that have tested efficacy, durability and safety of this approach over the long term. Moreover, evidence regarding the risks and benefits of bariatric/metabolic surgery in patients with diabetes and mild obesity is limited.

ARMMS-T2D researchers will obtain follow-up data from Type 2 diabetes patients with a BMI of 27 to 45, who were randomized to surgical or non-surgical diabetes management approaches. Bariatric and metabolic surgical procedures include gastric bypass, sleeve gastrectomy and gastric banding. About one-third of participants have a baseline BMI that is less than 35, which is considered mild to moderate obesity.

[Sangeeta Kashyap, M.D.](#), co-investigator and endocrinologist, [Cleveland Clinic Endocrinology and Metabolic Institute](#) said: “Despite advances in medical treatment, Type 2 diabetes remains a major cause of morbidity and mortality in the U.S. Metabolic surgery is a promising new option that may reduce complications of Type 2 diabetes. ARMMS-T2D will provide physicians and patients critical long-term results of surgery compared to medical treatment to better guide therapy.”

For all participants, researchers will focus on three main goals:

- Evaluate durability of glycemic control, assessed by HbA1c over time from baseline to seven years, between patients randomized to bariatric/metabolic surgery or medical and lifestyle therapy.
- Determine longer-term efficacy and safety outcomes in patients randomized to bariatric/metabolic surgery or medical and lifestyle therapy.
- Identify clinical predictors of diabetes remission and relapse.

The ARMMS-T2D study is funded by the NIH. The grant number is U01 DK114156.

About Cleveland Clinic

Cleveland Clinic is a nonprofit multispecialty academic medical center that integrates clinical and hospital care with research and education. Located in Cleveland, Ohio, it was founded in 1921 by four renowned physicians with a vision of providing outstanding patient care based upon the principles of cooperation, compassion and innovation. Cleveland Clinic has pioneered many medical breakthroughs, including coronary artery bypass surgery and the first face transplant in the United States. *U.S. News & World Report* consistently names Cleveland Clinic as one of the nation's best hospitals in its annual "America's Best Hospitals" survey. Among Cleveland Clinic's 51,000 employees are more than 3,500 full-time salaried physicians and researchers and 14,000 nurses, representing 140 medical specialties and subspecialties. Cleveland Clinic's health system includes a 165-acre main campus near downtown Cleveland, 10 regional hospitals, more than 150 northern Ohio outpatient locations – including 18 full-service family health centers and three health and wellness centers – and locations in Weston, Fla.; Las Vegas, Nev.; Toronto, Canada; Abu Dhabi, UAE; and London, England. In 2016, there were 7.1 million outpatient visits, 161,674 hospital admissions and 207,610 surgical cases throughout Cleveland Clinic's

health system. Patients came for treatment from every state and 185 countries. Visit us at clevelandclinic.org. Follow us at twitter.com/ClevelandClinic. News and resources available at newsroom.clevelandclinic.org.

About the Lerner Research Institute

The Lerner Research Institute is home to Cleveland Clinic's laboratory, translational and clinical research. Its mission is to promote human health by investigating in the laboratory and the clinic the causes of disease and discovering novel approaches to prevention and treatments; to train the next generation of biomedical researchers; and to foster productive collaborations with those providing clinical care. Lerner researchers publish 1,500 articles in peer-reviewed biomedical journals each year. Lerner's total annual research expenditure was \$260 million in 2016 (with \$140 million in competitive federal funding, placing Lerner in the top five research institutes in the nation in federal grant funding).

Approximately 1,500 people (including approximately 200 principal investigators, 240 research fellows, and about 150 graduate students) in 12 departments work in research programs focusing on heart and vascular, cancer, brain, eye, metabolic, musculoskeletal, inflammatory and fibrotic diseases. The Lerner has more than 700,000 square feet of lab, office and scientific core services space. Lerner faculty oversee the curriculum and teach students enrolled in the Cleveland Clinic Lerner College of Medicine (CCLCM) of Case Western Reserve University – training the next generation of physician-scientists. Institute faculty also participate in multiple doctoral programs, including the Molecular Medicine PhD Program, which integrates traditional graduate training with an emphasis on human diseases. The Lerner is a significant source of commercial property, generating 64 invention disclosures, 15 licenses, 121 patents, and one new spinoff company in 2016. Visit us at www.lerner.ccf.org. Follow us on Twitter at www.twitter.com/CCLRI.

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