

# Bariatric surgery, medication/lifestyle modification: Which has better long-term effect on diabetes

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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.

Provided by Cleveland Clinic

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