# Tulane University doctors treat first patients in pivotal study of new type 2 diabetes treatment

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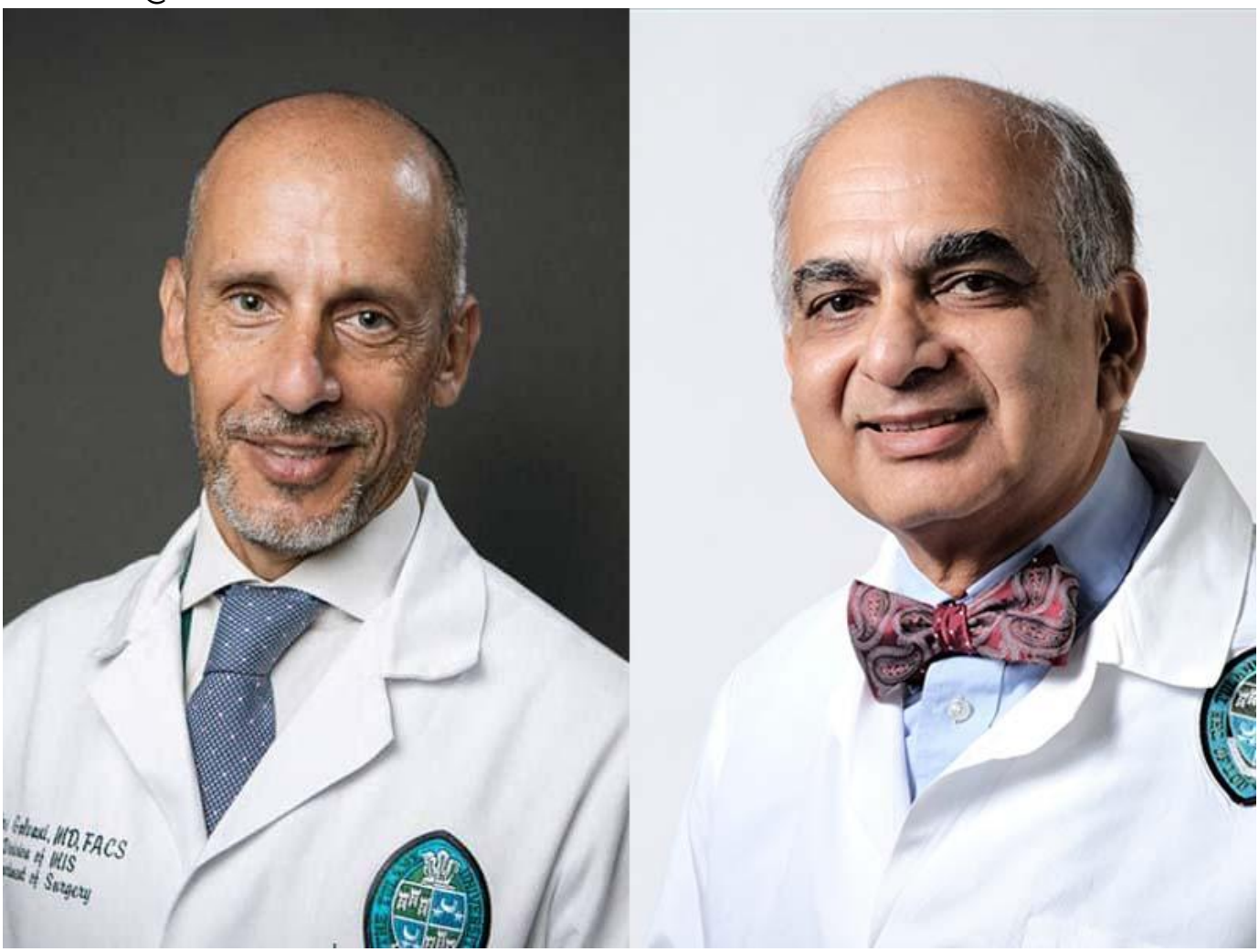

Dr. Carlos Galvani (left), chief of bariatric surgery at the School of Medicine, and Dr. Vivian Fonseca (right), assistant dean for clinical research at the School of Medicine.

Tulane University doctors are the first in the country to test a new outpatient treatment for type 2 diabetes that uses heat to resurface a key part of the upper intestine that plays a role in insulin resistance.

The procedure is part of the REVITA T2Di clinical study, a randomized clinical trial in patients with inadequately controlled type 2 diabetes. The study will evaluate

whether a one-time procedure called Revita® duodenal mucosal resurfacing (DMR) can help patients improve their blood sugar control and reduce or eliminate their need to take insulin.

“Revita DMR is designed to target and reduce the hormonal signals that lead to insulin resistance, the underlying metabolic defect of type 2 diabetes and other metabolic diseases. This means patients may be able to achieve glycemic control while eliminating insulin and the various side effects that come with insulin,” said Dr. Vivian Fonseca, assistant dean for clinical research at Tulane University School of Medicine and primary study investigator. “We’re excited to further test this breakthrough therapy at Tulane using our world-leading research and clinical capabilities.”

DMR is a minimally invasive endoscopic procedure that uses thermal energy to heat the lining of the duodenum, which is the part of the small intestine immediately after the stomach. The duodenum plays an important role in the control of Type 2 diabetes. Diets high in fat and sugar can cause the duodenal lining to thicken over time. The procedure removes these excess layers. After treatment, the duodenum begins to regenerate a new, healthy lining within a matter of days.

One key aspect of the Revita procedure, unlike insulin management, is that it does not rely on patient adherence or persistence to chronic therapy for its clinical effects. This means that the procedure and subsequently simplified treatment can potentially offer greater ease and convenience for patients with type 2 diabetes and their caregivers, said study investigator Dr. Carlos Galvani, who performed the procedures at Tulane.

“The Revita procedure is a cutting-edge diabetes treatment designed to be an outpatient, minimally invasive procedure that is performed by a trained endoscopist in less than an hour,” said Galvani, chief of bariatric surgery at Tulane University School of Medicine. “Patients in this study are able to resume normal activities by the very next day.”

The study is sponsored by Fractyl Health, a company on a mission to eradicate type 2 diabetes through development of disease-modifying therapies that target the organ-level root causes of the disease.

Revita DMR has been studied in clinical trials involving close to 300 patients. Revita DMR has received FDA Breakthrough Device Designation and a European Union CE

mark. In the United States, the device has not yet been authorized for marketing, but is the subject of an FDA-approved Investigational Device Exemption study.

Eligible participants receive all study-related health assessments at no cost. To learn more about the REVITA T2Di study and enrollment eligibility, visit revitastudy.com.