# Evaluation of the Efficacy and Safety of Duodenal Mucosal Resurfacing Using the Revita® System in Subjects With Type 2 Diabetes on Insulin Therapy

**Status:** Recruiting

## Eligibility Criteria

**Age:** 21 years to 70 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria:**

1. Male, and non-pregnant, non-lactating females 2. Age between 21 and 70 years (both inclusive) 3. Subjects with T2D on stable dose (up to maximally approved doses) of metformin and up to 2 ADAs (including either GLP1 or DPP-4i and/or, TZD), requiring a minimum of 20 units up to a maximum of 60 units of basal insulin 4. Glycosylated hemoglobin A1c (HbA1c) of 7.5-9.5% (both inclusive) confirmed at the end of at least 3 weeks stable run-in period 5. FPG ≥180 to <270 mg/dL (measured after overnight 8-hour fasting and 24-36 hours after the last dose of glargine) at the end of at least 3 weeks stable run-in period 6. Body Mass Index (BMI) ≥ 24 to ≤ 40 kg/m2 7. Women of child-bearing potential (WOCBP) should have negative urine beta human chorionic gonadotropin (hCG) pregnancy test and must agree to use two of the established contraceptive methods throughout the study duration 8. Able to sign an informed consent form and comply with study requirements.

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**Exclusion Criteria:**

1. Known case of absolute insulin deficiency as indicated by clinical assessment, and a fasting plasma C-peptide of <0.6 ng/ml 2. Any drugs or concomitant medications (such as psychoactive drugs such as carbamazepine, phenobarbital, sympathomimetics (ephedrine etc.), corticosteroids, anabolic steroids, and male sex hormones such as testosterone, etc.) that can interfere with glucose metabolism 3. Subjects who either are on SGLT2i, meglitinides, sulphonylurea (SUs), short or rapid acting insulin or any other class of ADA other than permitted baseline ADAs at the time of consent or who have a known or documented SGLT2i and/or metformin intolerance prior to the study 4. Recurrent or severe urinary tract or genital mycotic infections or history of GU infection within 4 weeks prior to informed consent 5. ALT >3 times upper limit normal values unless if associated with underlying NAFLD 6. Use of an investigational drug within 1 month or 5 half-lives (whichever is longer) before the screening 7. Diagnosed with type 1 diabetes or with a recent history of ketoacidosis 8. Ketosis-prone T2D 9. History of non-healing diabetic ulcers or amputations 10. History of more than 1 severe hypoglycemia episode or unawareness within past 6 months of screening 11. In case of two or more glucose alert values of ≤70 mg/dL (3.9 mmol/L) unless a clear correctable precipitating factor can be identified/clinically significant hypoglycemia with self-monitored or laboratory plasma glucose level < 54 mg/dL (3.0 mmol/L / severe hypoglycemic episode requiring third party assistance occurring during run-in period 12. Known intestinal autoimmune disease, as evidenced by either a positive anti-glutamic acid decarboxylase (GAD) test, including Celiac disease, or pre-existing symptoms of lupus erythematosus, scleroderma, or other autoimmune connective tissue disorder, which affects the small intestine 13. Secondary hypothyroidism or inadequately controlled primary hypothyroidism (thyroid stimulating hormone (TSH) value outside the normal range at screening) 14. Known history of thyroid cancer or hyperthyroidism who have undergone treatment within past 12 months or inadequately controlled hyperthyroidism 15. An uncontrolled endocrine condition such as multiple endocrine neoplasia etc. (except T2D) 16. Known history of a structural or functional disorder of the esophagus, including any swallowing disorder, esophageal chest pain disorders, or drug-refractory esophageal reflux symptoms, active and uncontrolled Gastroesophageal Reflux Disease (GERD) (grade 3 esophagitis or greater) 17. Known history of a structural or functional disorder of the stomach, including gastric ulcer, chronic gastritis, gastric varices, hiatal hernia (a large hiatal hernia or type II and higher paraoesophageal hernia) cancer or any other disorder of the stomach 18. Previous GI surgery that could affect the ability to treat the duodenum such as subjects who have had a Billroth 2, Roux-en-Y gastric bypass, gastric sleeve or other similar procedures or conditions 19. Known history of chronic pancreatitis or a recent history of acute pancreatitis within the past year 20. Presence of acute or chronic active hepatitis B or C (except if hepatitis C is cured) or cirrhosis; or hepatic decompensation/acute liver disease during the last 6 months; or alcoholic or autoimmune chronic hepatitis 21. Symptomatic gallstones or symptomatic kidney stones, acute cholecystitis 22. Clinically active systemic infection 23. Known immunocompromised status, including but not limited to individuals who have undergone organ transplantation, chemotherapy, or radiotherapy within the past 12 months, who have clinically significant leukopenia, who are positive for the human immunodeficiency virus (HIV), who are on potential immunosuppressants or whose immune status makes the subject a poor candidate for clinical trial participation in the opinion of the Investigator 24. History of active malignancy or partial remission from clinically significant malignancy within the past 5 years (except basal or squamous cell skin cancer or carcinoma in situ or those received curative treatment and in complete remission for 5 years or if subject confirmed as cancer free) 25. Known active coagulopathy, or current upper gastro-intestinal bleeding conditions such as ulcers, gastric varices, strictures, or congenital or acquired intestinal telangiectasia 26. Subjects with active helicobacter pylori infection (Subjects may be enrolled if they had history of h pylori infection and were successfully treated) 27. Known cases of anemia, thalassemia or conditions that affect red blood cell (RBC) turnover such as recent blood transfusion within 90 days 28. Use of anticoagulation therapy (such as warfarin, coumadin, novel oral anticoagulants [NOAC]) or anti-platelet agents (such as thienopyridine) which cannot be discontinued for 5-7 days or 2 drug half-lives before the procedure 29. Use of systemic glucocorticoids (excluding topical or ophthalmic application or inhaled forms) for more than 10 consecutive days within 90 days prior to the Screening Visit 30. Use of drugs known to affect GI motility (e.g., metoclopramide) 31. History of moderate to severe chronic kidney disease (CKD), with estimated glomerular filtration rate (eGFR) <45 mL/min/1.73m2 (estimated by Modification of Diet in Renal Disease [MDRD]) or end stage renal failure or on dialysis 32. History of myocardial infarction, stroke, or major event requiring hospitalization within the last 3 months prior to screening 33. History of new or worsening signs or symptoms of coronary heart disease (CHD) within the last 3 months 34. Known case of severe peripheral vascular disease 35. Known case of symptomatic heart failure with reduced ejection fraction (NYHA Class II-IV) requiring pharmacologic therapy to control symptoms 36. Clinically significant electrocardiogram (ECG) findings such as new clinically significant arrythmia or conduction disturbances that increases risk and requires intervention as determined by the investigator 37. Subjects who are at risk for pancreatitis particularly those with a recent fasting triglycerides value of > 600 mg/dL value done within past 3 months 38. Actively participating in a weight loss program and is currently not in the maintenance phase 39. General contraindications to deep or conscious sedation or general anesthesia or high risk as determined by anesthesiologist (e.g., ASA score 4 or higher) or contraindications to upper GI Endoscopy 40. History of any illicit alcohol or substance abuse 41. Use of weight loss medication such as Meridia, Xenical, or over the counterweight loss medications or other prescribed medications used specifically for purpose of weight loss 42. Use of Dietary supplements or herbal preparations that may have unknown effects on glycemic control, risk of bleeding 43. Participating in another ongoing clinical trial of an investigational drug or device 44. History of non-adherence to treatment in the previous 6 months, as determined by the investigator based on patient history, HbA1c value and/or drug accountability 45. Any other mental or physical condition which, in the opinion of the investigator, makes the subject a poor candidate for clinical trial participation 46. Unwilling or unable to perform SMBG, complete the subject glycemia diary, or comply with study visits and other study procedures as required per protocol 47. Recovered from severe COVID-19 infection (requiring hospitalization) however still have persistent long COVID-19 symptoms (i.e., they have not recovered for several weeks or months since the start of symptoms that were suggestive of COVID-19, irrespective if they are tested or not).

## Conditions & Interventions

**Interventions:**

Device: Duodenal Mucosal Resurfacing (DMR), Device: Duodenal Mucosal Resurfacing (Sham)

**Conditions:**

Type 2 Diabetes

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**Keywords:**
Type 2 Diabetes, Diabetes Mellitus, Glucose Metabolism Disorders, Metabolic Diseases, Endocrine System Diseases, Revita System, Duodenal Mucosal Resurfacing, Insulin-Dependent Diabetes Mellitus

## More Information

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