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Effect of Tirzepatide on the progression of coronary atherosclerosis using MDCT: Rationale and design of the Tirzepatide treatment on coronary atherosclerosis progression (T-PLAQUE)

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Abstract

Introduction: Tirzepatide is a novel once-week dual GIP/GLP-1 RA agonist approved for T2DM and has proven to reduce cardiovascular events. The goal of this trial is to assess how tirzepatide affects the progression of atherosclerotic plaque as determined by multidetector computed tomography angiography (MDCTA).

Methods: This trial is a double-blind, randomized, prospective, placebo-controlled multi-center phase IV trial. Participant eligible for the study will be adults with T2DM between 40 and 80 years of age who have HbA1c ≥7.0% to ≤10.5% and at least 20% stenosis in major epicardial vessel on CCTA. Baseline examination will include the results of their demographics, lab tests, coronary calcium, as well as coronary plaque volume/composition. Following randomization, tirzepatide or placebo will be given at a weekly dose of 2.5 mg, and a fixed dose-escalation strategy will be followed. Patients will undergo quarterly visits for safety assessments and labs, and follow up with repeat CCTA at 1 year.

Discussion: This study evaluate the anti-atherogenic potential of tirzepatide, providing a mechanism of CV benefit. This is crucial to our understanding of DM treatment and CVD since plaque progression portends worse outcomes in these populations. MDCTA is a noninvasive method that assesses the volume, composition, and degree of coronary vessel stenosis.

Conclusion: This study will be the first study to assess the effects of tirzepatide on atherosclerotic plaque progression measured by MDCTA in participants with T2DM and it will also assess whether the effects correlate with HbA1c, weight reduction, and inflammatory markers.