

Title

A randomized, double-blind, placebo-controlled, parallel-group, multicentre study to evaluate the effects of sotagliflozin on clinical outcomes in hemodynamically stable patients with type 2 diabetes post worsening heart failure

Acronym

Sotagliflozin in Patients with T2DM post worsening Heart Failure

Principal/Lead Investigator

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Participating Sites

Morrison Hospital

Study Summary

Heart failure is a common comorbidity and complication of Type 2 Diabetes. Patients with Heart Failure have particularly poor outcomes and 5-year survival rates of <25%. The condition known as post-worsening heart failure represents a specific unmet medical need in patients with Type 2 Diabetes, since the rates of hospitalization for Heart Failure in patients with diabetes are substantially higher compared to those for Heart Failure patients without diabetes.

Sotagliflozin is a dual inhibitor of both sodium-glucose linked transporter-2 (SGLT2) and sodium-glucose linked transporter-1 (SGLT1). Sotagliflozin works in the kidney to allow more sugar to be lost in the urine, and also in the intestine to prevent absorption of sugars. In this way, it is thought to help in lowering blood sugar in diabetes. Recent data point to the beneficial effects of SGLT2 inhibitors in reducing cardiovascular death and Heart Failure in patients with Type 2 Diabetes.

This study is designed to demonstrate whether sotagliflozin reduces the cardiovascular deaths and hospitalization for heart failure as compared to placebo in diabetic patients after admission for Worsening Heart Failure. Around 4,000 patients will be enrolled worldwide, with 25 planned in the UK, and will be randomised to either Sotagliflozin or placebo.

UKCTG Number

34050

Study Sponsor

Sanofi-aventis Recherche & Developpement