Evolocumab reduces LDL cholesterol in a global population of patients with type 2 diabetes

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Video Abstract

Keywords: evolocumab, BERSON clinical trial, phase 3, dyslipidaemia, mixed dyslipidaemia, hyperlipidaemia, statin, atorvastatin, type 2 diabetes, diabetes mellitus, efficacy, safety, lipid, LDL-C, low-density lipoprotein, cholesterol, myocardial infarction, stroke, cardiovascular disease, Instituto Medico DAMIC

Posted Date: September 20th, 2019

DOI: <https://doi.org/10.21203/rs.2.14996/v1>

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Abstract

Diabetes is a major risk factor for myocardial infarction, stroke, and other cardiovascular diseases. The prime target for reducing cardiovascular risk is low-density lipoprotein, or LDL. LDL cholesterol has been linked to cardiovascular events in patients with type 2 diabetes. While statins have long been the primary treatment for reducing LDL, many patients are unable to reach recommended levels with a statin alone or are unable to take an effective dose. That places them at an especially high risk for cardiovascular disease. Now, a new study reports the efficacy and safety of evolocumab on top of statins in patients with both type 2 diabetes and hyperlipidemia or mixed dyslipidemia. The double-blind, phase 3 trial was conducted in patients from 10 different countries over a treatment period of 12 weeks. More than 980 patients were randomized to one of four subcutaneous treatments: 140 mg of evolocumab every 2 weeks, 420 mg of evolocumab monthly, or placebo at either of those frequencies. All patients received 20 mg of atorvastatin oral daily. Compared with baseline levels, evolocumab at either dose plus atorvastatin 20 mg significantly reduced mean LDL cholesterol by 62 to 69%—a reduction of 65 to 72% compared to atorvastatin 20 mg plus placebo. And approximately 90% of patients who received evolocumab with background atorvastatin 20 mg were able to achieve LDL cholesterol levels below 1.8 mmol/L, or 70 mg/dL. The overall incidence of adverse events was similar between the drug and placebo groups. And over time, there were no clinically meaningful differences in glycemic parameters such as fasting serum glucose or hemoglobin A1C. The study was limited by a relatively short duration and a small patient pool for assessing the safety and sustained LDL-lowering effect of evolocumab. Another shortcoming was the use of a non-intensive statin, atorvastatin 20 mg. While standard practice in China, where nearly half of the patients were enrolled, using atorvastatin 20 mg is a more conservative approach than in other regions. That limits comparison with other global studies, which may have used higher doses of statin therapy. Still, the findings are encouraging. Safe, well-tolerated, and able to significantly reduce LDL cholesterol levels with no notable effects on measures of glycemic control, evolocumab represents a promising treatment for patients with type 2 diabetes at high risk for cardiovascular disease.