

Diabetes drug Liraglutide proves mettle in cardiovascular trial

A clinical trial focusing on the impact of a blockbuster diabetes drug, liraglutide, on the cardiovascular system found that it holds significant benefit for diabetes patients at risk of cardiovascular disease.

The results follow closely on the success of empagliflozin, another type II diabetes drug that had similarly positive effect on cardiovascular outcomes in the [EMPA-REG Outcome](#) study. Physicians hope that these studies will help optimize treatment protocols that address both diabetes and its common cardiovascular counterpart.

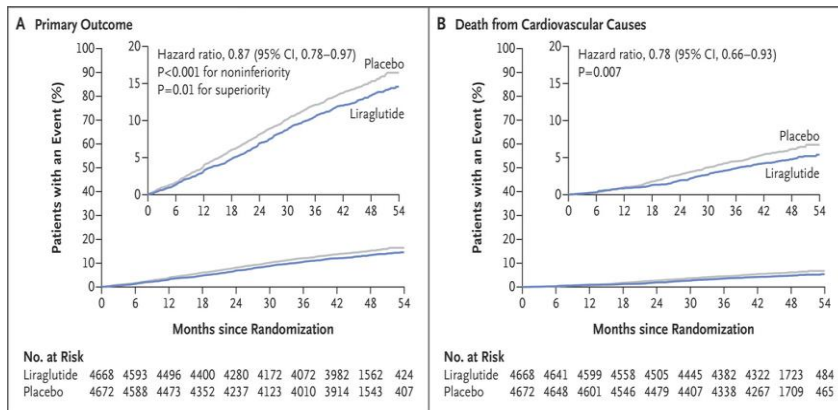


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Primary and Exploratory Outcomes. The primary composite outcome in the time-to-event analysis was the first occurrence of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke. The cumulative incidences were estimated with the use of the Kaplan-Meier method, and the hazard ratios with the use of the Cox proportional-hazard regression model. The data analyses are truncated at 54 months, because less than 10% of the patients had an observation time beyond 54 months. The insets show the same data on an enlarged y axis.

Also in 2010, researchers in the United States and Europe launched the [Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results \(LEADER\)](#) trial. In the randomized, double blind trial, the researchers followed 9340 patients, including 4672 in the control group, for a median 3.8 years.

Among those taking liraglutide, 4.7% died during the period of monitoring, compared to 6.0% in the placebo group—a significantly lower rate. The overall death rate from all causes was also significantly lower too, at 8.2% compared to 9.6%. Two other primary endpoints—the number of cases of myocardial infarction and stroke—were lower in the liraglutide group, but not significantly so.

Overall a success, the trial leaves open some puzzling questions, such as why patients without preexisting cardiovascular disease didn't seem to benefit. And a slight increase in pancreatic cancer rates raises the question of how closely its use needs to be monitored for adverse effects.

The positive results are another feather in liraglutide's cap. While it failed to show benefit for type 1 diabetes patients, the drug has proven effective in curbing weight gain, and it had positive early results in treating a liver disease known as NASH (non-alcoholic steatohepatitis).

Novo Nordisk is already moving briskly to expand its s-1 pipeline to attack heart disease. In April the company [announced results](#) of the SUSTAIN 6 trial, which tested semaglutide, another GLP-1 analogue. Patients taking semaglutide witnessed similar reductions in death from cardiovascular disease and overall death. With liraglutide's patent set to run out in 2017, semaglutide might be the company's best bet to follow up on the promise of GLP-1 analogues.

Diabetes has long been known to be a risk factor for cardiovascular disease. Cardiovascular disease accounts for the deaths of roughly [two-thirds](#) of all diabetics, and diabetes elevates the risk of dying from heart disease between an [estimated two to eight times](#). Some [30% of acute myocardial infarction patients have diabetes](#)—five times higher than the general population. There has been some evidence that success in controlling diabetes can help patients escape cardiovascular breakdown. Now rigorous studies are starting to back that up.

Liraglutide, produced by Nova Nordisk, is an analogue of human glucagon-like peptide 1 (GLP-1), which mimics incretin hormones that lower blood sugar. It was approved in Europe in 2008 and the United States in 2010 to help type II diabetes patients keep control of their glycemic levels.