

Diabetes Trial Deaths End Part of Study

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A diabetes drug trial was halted recently after it was determined that trial participants receiving aggressive diabetes treatment were dying at a higher rate than those who did not receive intensive therapy. However, researchers involved in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial were quick to assert that the controversial drug Avandia was not to blame for the deaths, and that the overly aggressive treatment administered to some participants was most likely the cause of the deaths.

The ACCORD trial, sponsored by the U.S. National Heart, Lung, and Blood Institute (NHLBI), began in 2001 at 77 sites in the United States and Canada with the enrollment of 10,251 patients with type 2 diabetes who were at high risk for heart attack or stroke because they had at least two risk factors, including high blood pressure, high cholesterol or obesity. Those in the trial received either medications to aggressively lower their blood sugar below recommended levels, or standard treatment to control their disease. The goal of the aggressive treatment group was to lower blood sugar levels -- a measure known as hemoglobin A1c -- to below 6 percent, far below the current target of under 7 percent and closer to what is seen in non-diabetics. The researchers said they would now adjust the ACCORD trial so the blood sugar of patients would not be lowered so much.

Yesterday, it was announced that 257 people who received the intensive therapy had died, compared with 203 in patients in a standard treatment group. Among the 257 deaths in the aggressive therapy group, 50 percent were due to heart attacks or other cardiovascular causes. Patients in the intensive treatment group had fewer nonfatal heart problems, but they had more unexpected sudden deaths, even without a clear heart attack. While they could not pinpoint the reason for the heightened risk, they all but ruled out any of the diabetes drugs -- including Avandia -- that were used.

"Because of the recent concerns raised with regard to rosiglitazone, we specifically analyzed the data to try and determine whether there was any link between this particular medication and the increased deaths we were seeing in the ACCORD intensive treatment group," Dr. William Friedewald, chairman of the ACCORD Steering Committee. "At this time, we have found no link, and thus the use of rosiglitazone does not seem to explain the increased mortality."

Avandia has been a subject of controversy since May 2007, when an analysis of 42 clinical trials published by the Cleveland Clinic showed that patients taking the drug had a 43-percent higher risk of having a heart attack.