

Major Study Shows High-Dose Atorvastatin Drugs Use Reduces Risk of Second Stroke

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In a large-scale clinical study of patients with prior history of a stroke or transient ischemic attack (TIA), but no known coronary heart disease, treatment with the statin drug atorvastatin (sold under the brand name Lipitor) was found to reduce the risk of stroke and major coronary events. The study – funded by Pfizer, Inc., manufacturer of Lipitor – will be published in the August 10 issue of the New England Journal of Medicine.

The study comprised 4,731 men and women who had experienced a stroke or TIA within six months prior to trial enrollment, and followed them for an average of five years. In the population studied, atorvastatin reduced the risk of stroke by 16 percent and the risk of major coronary events by 35 percent. The UC San Diego Medical Center was one of more than 200 clinical sites around the world that participated in the study between 1998 and 2005.

“This is important information for physicians and patients, because – once a patient suffers a stroke – current treatment options are limited,” said Justin A. Zivin, MD, PhD, professor of neurosciences at the University of California, San Diego (UCSD) School of Medicine.

Zivin was on the independent steering committee for the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) study. SPARCL is the first large, placebo-controlled study to investigate patients with prior history of stroke or TIA but without established coronary heart disease. Brett Meyer, M.D., assistant professor of neurosciences at UC San Diego Medical Center and co-director of the UC San Diego Stroke Center, was principal investigator for the San Diego trial.

Atorvastatin is one of a class of lipid-lowering drugs that reduce serum cholesterol levels by inhibiting a key enzyme involved in the biosynthesis of cholesterol. Statin cholesterol-lowering drugs are among the most prescribed drugs in the United States. According to Consumer Reports, Lipitor was the #1 best-selling drug in the country in 2004, with 75 million prescriptions sold.

Patients in the trial had normal or mildly elevated cholesterol levels, and were treated with either 80 mg. of atorvastatin or a placebo to determine if the drug would reduce the occurrence of

another stroke. The majority of these patients (94%) were already being treated with aspirin or other anti-platelet therapies, and 69% took blood pressure-lowering medications. Patients continued with these therapies during the trial.

Of those patients who suffered a stroke while enrolled in the trial, 85% had an ischemic stroke – the most common type of stroke, where the blood supply to a part of the brain is suddenly blocked. A separate analysis of the SPARCL data designed and conducted after the study ended showed that patients taking atorvastatin experienced a 22% reduction in the risk of ischemic stroke. This analysis also found that patients in the atorvastatin group experienced a very slight increase in the number of hemorrhagic strokes – 2.3 %, compared with 1.4% of the control group – a number deemed too few to draw meaningful conclusions.

In SPARCL, the 80mg dose of atorvastatin was reported to be well-tolerated, with low incidence of adverse effects sometimes reported with statin use, such as liver or kidney problems and muscle weakness.

“The findings seem to show that almost anyone who has had a stroke or TIA should be on atorvastatin,” said Zivin. “This isn’t the only thing, but is one of the therapies that physicians can use to help their patients prevent a second stroke or other coronary event.”

Patients should consult with their doctor about the use of atorvastatin to reduce the risk of strokes, adds Zivin, who receives consulting fees from Pfizer. For more information, patients can also contact the UC San Diego Stroke Center at (858) 657-8540.

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