Study finds stroke risk from anemia drug Aranesp

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(AP) -- A new study raises fresh safety concerns about widely used anemia medicines, finding that the drug Aranesp nearly doubled the risk of stroke in people with diabetes and chronic kidney problems who are not yet sick enough to need dialysis.

The study is the largest ever of these blood-boosting drugs and the only one that compared them to a dummy treatment. The medicines have become blockbuster sellers because they lessen the need for transfusions, but their ability to prevent heart attacks, kidney failure or other problems have not been proven.

Over the last two years, the federal Food and Drug Administration has repeatedly strengthened warning labels on Aranesp, Epogen and Procrit as concerns rose that they may worsen survival in certain cancer patients, especially at higher doses. Amgen Inc. of Thousand Oaks, Calif., makes all three drugs, although New Brunswick, N.J.-based Johnson & Johnson sells Procrit.

The new study tested Aranesp in a different group of patients: 4,038 people with Type 2 diabetes, kidney problems and moderate anemia - problems that often go hand in hand. The goal was to see if the drug could prevent heart attacks, heart failure, strokes or the need for dialysis.

It not only failed to do that, but "we uncovered a risk that I think is substantial for stroke," said study leader Dr. Marc Pfeffer, a heart specialist at Brigham and Women's Hospital in Boston.

Strokes occurred in 101 patients given Aranesp and 53 patients given dummy shots. Looked at another way, the risk of suffering a stroke was about 1 percent per year in the placebo group and about 2 percent in those given Aranesp.

For many people, "this risk will outweigh its potential benefits," the study's authors conclude.

Results were published online Friday by the New England Journal of Medicine and were to be presented at a conference of kidney specialists in San Diego. Amgen sponsored the study. Pfeffer has consulted for the company and two authors work for it.

Dr. Roger Perlmutter, Amgen's head of research and development, said the magnitude of stroke risk "surprised us." The potential risk of stroke has been listed on Aranesp's label since the drug was approved in 2001, but "we will definitely update the label" because of the new study's results, he said.

Aranesp did reduce the need for transfusions - 297 people on the drug needed them versus 496 of those getting dummy shots. However, there was only a modest improvement in how fatigued people said they felt in the Aranesp group.

The study's results may not apply to people already on dialysis, Dr. Philip Marsden of St. Michael's Hospital and the University of Toronto in Ontario, Canada, writes in an editorial in the medical journal. For them, the quality of life improvement from fewer transfusions may be greater.

Also on Friday, the New York Attorney General's office said it and 15 states were suing Amgen, claiming the company gave kickbacks and weekend retreats to medical providers to help boost Aranesp sales, and

encouraged them to bill third parties, including Medicaid, even though the drug was available to them at no cost.

A statement by the company said the allegations were "without merit."