

[Aranesp Associated With Increased Risk For Stroke In Patients With Diabetes And Chronic Kidney Disease](#)

TREAT Study Revealed, Also, That This Amgen Anemia Drug Was No Better Than Placebo In Reducing Deaths Or Cardiovascular Problems

(Posted by Tom Lamb at www.DrugInjuryWatch.com on November 6, 2009; see <http://bit.ly/2raVRw>)

The anemia drug Aranesp (darbepoetin alfa) might cause an increased risk for stroke in patients with diabetes and chronic kidney disease, according to the results from the Trial to Reduce Cardiovascular Events with Aranesp Treatment (TREAT), a new study that was published in the October 30, 2009 edition of the *New England Journal of Medicine (NEJM)* and presented recently at the annual meeting of the American Society of Nephrology.

As background, patients with type 2 diabetes and kidney disease often become anemic. In turn, heart and kidney problems can be accelerated by anemia. Accordingly, doctors have long prescribed Aranesp and other erythropoiesis-stimulating agent (ESA) drugs based on the belief that treating the anemia would improve patient's prognosis.

In an October 31, 2009 *Boston Globe* article, "[Researchers question anemia drug benefits](#)", reporter Elizabeth Cooney provides a good summary of the unexpected results from this TREAT study and the implications of those results:

The study, led by Boston researchers, is the first trial to compare this class of anemia drugs with a placebo in the ability to prevent death and serious complications - even though the drugs have been in use for decades.

"The risks of the therapy were bigger than we thought, namely stroke, and the benefits were less than we thought, in quality of life," said Dr. Marc Pfeffer, a cardiologist at Brigham and Women's Hospital who led an international group studying Aranesp, which raises red blood cell levels....

The study confirmed that patients taking Aranesp required fewer blood transfusions and suffered less fatigue, but other hoped-for outcomes were not seen.

Dr. Steven Woloshin of the Dartmouth Institute for Health Policy and Clinical Practice said the findings reinforce a crucial message in medicine.

"This current study is an important reminder of how important it is not to assume the treatments work, but to prove them," said Woloshin, who was not involved in the study. Aranesp, made by California-based Amgen, was approved by the Food and Drug Administration in 2001 for use in kidney patients, but a similar drug also made by Amgen has been prescribed for 20 years.

The *NEJM* article about this TREAT study concerning Aranesp, "[A Trial of Darbepoetin Alfa in Type 2 Diabetes and Chronic Kidney Disease](#)", was accompanied by an editorial, "[Treatment of Anemia in Chronic Kidney Disease — Strategies Based on Evidence](#)", from Philip A. Marsden, M.D.

Amgen, the drug company that makes Aranesp, issued a press release about the TREAT study results, "[Large Study of Anemia Treatment in Chronic Kidney Disease Patients Not on Dialysis Published in the New England Journal of Medicine Failed to Meet Primary Efficacy Endpoints](#)", which includes this statement:

Amgen has shared this information with global regulatory authorities and anticipates that the TREAT results will be included in labeling once discussions are complete.

We will be watching for this revised package insert, or label, for Aranesp which may or may not be announced by means of a so-called "Dear Doctor" letter.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.

<http://www.DrugInjuryWatch.com>