

Anemia drug not helpful for kidney disease patients

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An international study authored by a UT Southwestern Medical Center researcher has concluded that the anemia drug darbepoetin alfa works no better than a placebo in several other applications previously thought to be promising.

Darbepoetin alfa is one of a class of drugs used to increase red blood cells in patients with type 2 diabetes, chronic kidney disease and anemia, but in a study of 4,038 patients, it did little to reduce cardiovascular problems, death or even the need for dialysis.

Patients have used the drug and other similar drugs for at least a decade to improve the symptoms of anemia.

"We were disappointed that the drug didn't make a difference," said Dr. Robert Toto, professor of internal medicine at UT Southwestern and senior author of the study in *The New England Journal of Medicine*. "We set out doing this trial to prove whether treatment of anemia would help our patients."

Researchers also found that subjects who took the drug were nearly twice as likely to have a stroke as those who received a placebo - 101 subjects compared with 53.

"This is a surprise," Dr. Toto said. "Clinicians should not expect that treatment of anemia with darbepoetin and other drugs in its class will reduce their risk of cardiovascular events or prevent their kidney disease from progressing. If a clinician is treating a patient for fatigue and other symptoms of anemia and the symptoms do not improve, they should consider stopping the drug, because it may expose the patient to increased risk of stroke."

Chronic kidney disease, type 2 diabetes and anemia affect about 1 million people in the U.S., he said. Drugs such as darbepoetin alfa for treating anemic patients on dialysis (in the final stage of

kidney disease) were approved in the late 1980s. Soon afterward, accepted guidelines suggested using the drug with chronic kidney disease patients not on dialysis in hopes of improving symptoms, [cardiovascular death](#) rates and preventing chronic kidney disease from progressing to dialysis.

While studies were done in an attempt to determine optimal hemoglobin levels using such drugs in these patients, no trial was conducted comparing the drug with a placebo, until TREAT - Trial to Reduce Cardiovascular Events with Aranesp Therapy.

"From a scientific perspective, TREAT is the most rigorous," Dr. Toto said. "It's a randomized, double-blind, placebo-controlled trial."

From August 2005 until March 2009, researchers from 24 countries gave subjects with [chronic kidney disease](#), [type 2 diabetes](#) or [anemia](#) either a placebo or darbepoetin alfa. Twenty four subjects were from UT Southwestern.

Cardiac death or events occurred in 31 percent of the darbepoetin alfa group and in 29 percent of the placebo group. Kidney disease death or progression to dialysis occurred in 32 percent of the darbepoetin alfa group and in 31 percent of the placebo group.

Researchers did find a modest decrease in reported fatigue levels and a decrease in the need for blood transfusion in subjects taking darbepoetin alfa.

Provided by UT Southwestern Medical Center

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