

GOD Bless America
Best Health Care Medical Group, Inc.
Professor Mike Mirahmadi, M.D.
Diplomate, American Board of Internal Medicine & Nephrology
Clinical Professor of Medicine at UCLA

Darbepoetin α in Patients with Type 2 Diabetes, Chronic Kidney Disease, and Anemia

The drug provides little benefit and might cause harm.

Do patients with type 2 diabetes, chronic kidney disease, and anemia benefit from erythropoiesis-stimulating agents (ESAs)? To address this question, industry-supported investigators randomized 4038 patients (median age, 68; 58% women) with type 2 diabetes, chronic kidney disease (glomerular filtration rate, 20–60 mL/minute/1.73 m²), and hemoglobin level \leq 11.0 g/dL to the ESA darbepoetin α (Aranesp; to achieve a hemoglobin level of approximately 13 g/dL) or to placebo. Patients in the placebo arm received "rescue" darbepoetin α when their hemoglobin levels dropped below 9 g/dL.

After an average follow-up of 29 months, median hemoglobin levels were significantly higher with darbepoetin α (12.5 g/dL) than with placebo (10.6 g/dL). Correspondingly, significantly fewer darbepoetin α recipients received red-cell transfusions. However, the incidences of both primary endpoints — a composite of death or adverse cardiovascular event, and death or end-stage renal disease — were the same for both groups. Furthermore, stroke and thromboembolic events were more common with darbepoetin α .

Comment: Darbepoetin α provides little benefit and might cause harm in patients with type 2 diabetes, chronic kidney disease, and anemia. Previous trials indicated that target hemoglobin levels of 13–15 g/dL were associated with excess thrombotic events ([JW Gen Med Nov 15 2006](#)); the current results are consistent with those findings. Indeed, whether a safe target hemoglobin level exists is unclear. In the absence of randomized trial data to guide the use of ESAs for specific clinical situations, clinicians should not presume that these agents are safe and beneficial in patients with anemia.

— [Paul S. Mueller, MD, MPH, FACP](#)

Published in [Journal Watch General Medicine](#) November 3, 2009

Citation(s):

Pfeffer MA et al. A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease. *N Engl J Med* 2009 Oct 30; [e-pub ahead of print]. (<http://dx.doi.org/10.1056/NEJMoa0907845>)