

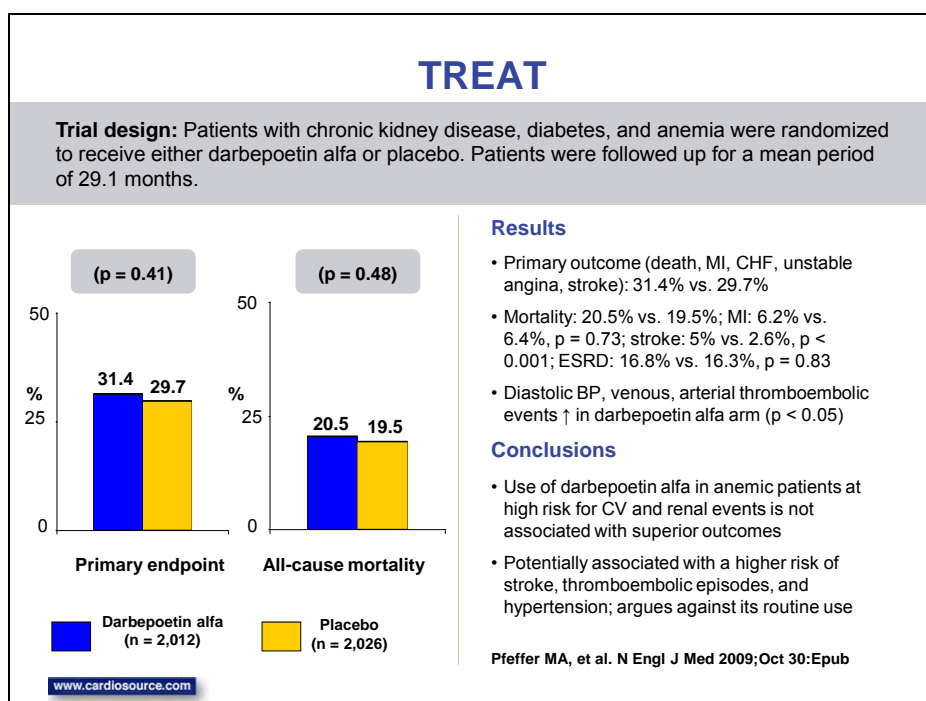
Trial to Reduce Cardiovascular Events With Aranesp Therapy (TREAT Trial)

This trial sought to test the hypothesis that the use of erythropoiesis-stimulating agents (ESAs) in pts with diabetes and chronic kidney disease (CKD) who were anemic and not on dialysis would be associated with improved outcomes.

A total of 4,038 pts were randomized, 2,012 to darbopoetin alfa (aranesp) and 2,026 to placebo. Baseline characteristics were fairly similar between the two groups. The median duration of diabetes was about 15.4 yrs.

The primary endpoint of death, MI, unstable angina, HF, or stroke was similar between the aranesp and placebo arms. Individual endpoints were similar between the two arms, except stroke ($p < 0.001$), which was higher in the aranesp arm. The renal composite endpoint of ESRD or death was similar between the two arms. Diastolic BP was higher in the aranesp arm ($p < 0.001$). There was a trend toward a higher incidence of HTN in the aranesp arm ($p = 0.07$). Venous ($p = 0.02$) and arterial ($p = 0.04$) thromboembolic events were more frequent in the aranesp arm.

The results indicate that the routine use of ESAs in pts with diabetes and CKD not on dialysis and concomitant anemia is not associated with a reduction in renal and CV events over an intermediate period of FU (29.1 mons). Risk of venous and arterial thromboembolic events, as well as stroke, and a trend toward HTN were more frequent with the use of darbepoetin alfa. These data are very important, and disagree against the routine use of ESAs in pts with diabetes, CKD, and anemia.



Pfeffer MA, et al. *N Engl J Med* 2009;361:2019-32.