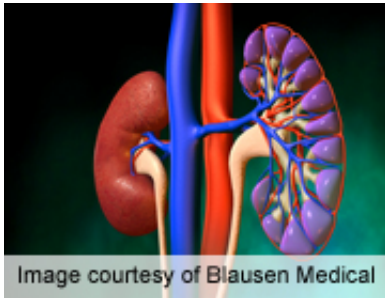


ASN: Bardoxolone methyl no benefit in T2DM, stage 4 CKD

11 November 2013



(HealthDay)—Bardoxolone methyl does not reduce the risk of end-stage renal disease (ESRD) or cardiovascular death in patients with type 2 diabetes mellitus and stage 4 chronic kidney disease, according to a study published online Nov. 9 in the *New England Journal of Medicine*. This research was published to coincide with the annual meeting of the American Society of Nephrology (Kidney Week), held from Nov. 5 to 10 in Atlanta.

Dick de Zeeuw, M.D., Ph.D., from the University of Groningen in the Netherlands, and colleagues randomized 2,185 patients with type 2 diabetes mellitus and stage 4 chronic kidney disease to receive bardoxolone methyl or placebo. Participants were followed for the primary composite outcome of ESRD or [cardiovascular death](#).

On the recommendation of the independent data and safety monitoring committee, the trial was terminated early, with a median follow-up of nine months. The researchers found that the primary composite outcome occurred in 6 percent of the 1,088 patients assigned to bardoxolone methyl and 6 percent of the 1,097 assigned to placebo. Significantly more patients in the bardoxolone methyl group were hospitalized for or died from

heart failure compared with the [placebo group](#) (96 versus 55 patients; hazard ratio, 1.83).

"Among patients with type 2 diabetes mellitus and stage 4 [chronic kidney disease](#), bardoxolone methyl did not reduce the risk of ESRD or death from cardiovascular causes," the authors write.

The study was funded by Reata Pharmaceuticals, a manufacturer of bardoxolone methyl.

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