

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

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(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 <u>cardiovascular death</u>.



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 <u>chronic</u> <u>kidney disease</u>, 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.

More information: Abstract

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