

Strategy suggests combining surrogate markers for kidney disease progression in clinical trials

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Change in urinary albumin:creatinine ratio (UACR) and glomerular filtration rate (GFR) slope are markers that are individually used as

surrogates of chronic kidney disease progression in clinical trials. Investigators recently developed a strategy that combines information from the treatment effects on the two to improve the prediction of treatments' effects on patient outcomes. Their research will be presented at ASN Kidney Week 2022 November 3–November 6.

The scientists used data from 41 randomized controlled trials of chronic kidney disease progression to develop their strategy and then applied the results to the design of a [phase 2](#) trial to assess design implications (such as sample size and follow-up time) for using UACR change and GFR slope individually or in combination.

The analysis revealed that in phase 2 [clinical trials](#) with sample sizes of 100–200 patients per arm or follow-up times ranging between 1 and 2 years, combining UACR change and GFR slope improves predictions of treatments' effects on clinical endpoints.

"Currently, UACR change and GFR slope are often evaluated as separate endpoints in phase 2 trials; however, it is not clear how to integrate the information provided by these two endpoints," said corresponding author Tom Greene, Ph.D., of the University of Utah. "This work presents a 2-step methodology for addressing this problem. In the first step, a Bayesian model is used to characterize the relationships among the treatment effects on UACR, GFR slope, and the clinical endpoint across previous randomized trials. In the second step, this model is used to provide a unified estimate of the probability of clinical benefit based on the estimated effects of the [treatment](#) on UACR change and GFR slope in a new phase 2 trial."

More information: Study: "Change in albuminuria and GFR slope as joint surrogate endpoints for kidney failure—Implications for phase 2 trials"

Provided by American Society of Nephrology

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