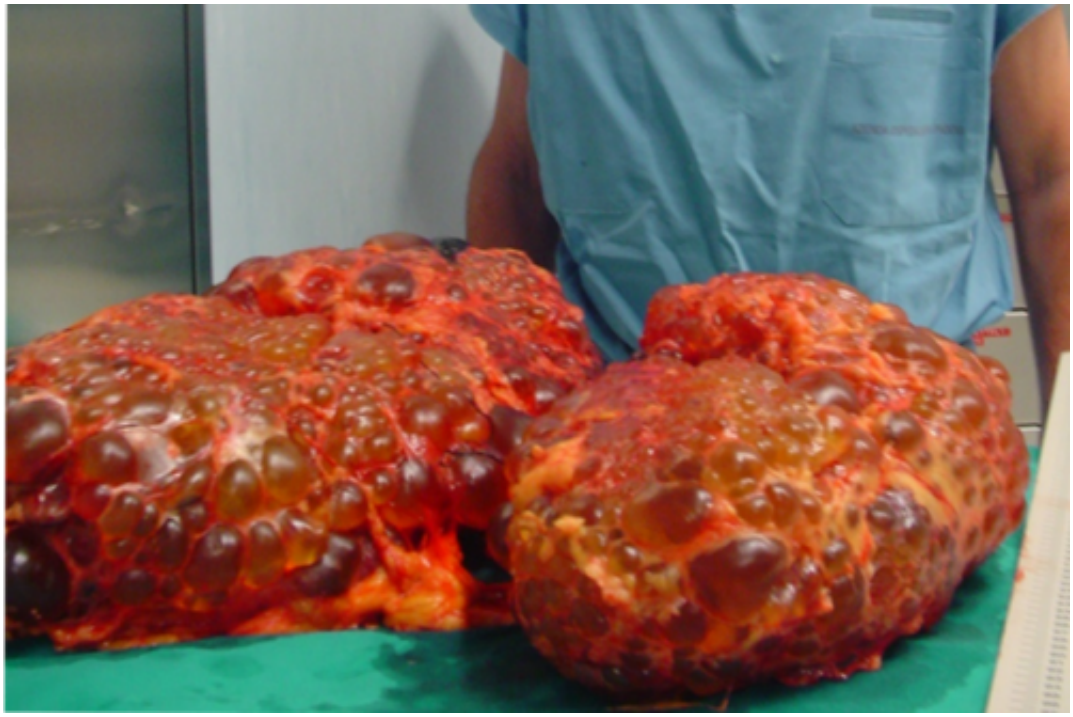
Two drugs are no more effective than one to treat common kidney disease

November 15 2014



Kidneys affected by polycystic kidney disease. Credit: *New England Journal of Medicine* 2010

Using two drugs was no more effective than a single drug in slowing disease progression in people with autosomal dominant polycystic kidney disease (ADPKD), according to two studies funded by the National Institutes of Health (NIH). One of the studies also showed that rigorous blood pressure treatment slowed growth of kidney cysts, a marker of

ADPKD, but had little effect on kidney function compared to standard blood pressure treatment.

The results of the HALT-PKD Clinical Trials Network studies will be published online November 15 in two papers in the *New England Journal of Medicine* to coincide with presentation at the American Society of Nephrology annual meeting.

"Enlarged cysts in kidneys can lead to reduced kidney function and eventually kidney failure, where the only treatment is dialysis or transplantation," said study author Michael Flessner, M.D., Ph.D., a program director at the NIH's National Institute of Diabetes and Digestive and Kidney Diseases, which funded the trial. "The HALT-PKD findings show that people with polycystic kidney disease do not need to take both of the drugs studied to slow their rate of kidney cyst growth and decline in kidney function."

The HALT-PKD trial enrolled volunteers to test whether a combination of commonly used FDA-approved drugs, lisinopril and telmisartan, could shrink kidney cysts and therefore slow progression of ADPKD, a genetic disorder characterized by growth of fluid-filled cysts in the kidneys. Within the trial, one study examined 558 people with early-stage ADPKD and relatively healthy kidneys. The other study treated 486 people with more advanced disease and decreased kidney function. In each study, half of participants were randomly assigned to receive lisinopril and telmisartan, while the other half received lisinopril plus a placebo. In both studies, adding the second drug did not change kidney function or rate of increase in kidney cyst size.

In the study of people with early ADPKD and healthy kidneys, researchers also tested if decreasing blood pressure below usual targets would slow progression of ADPKD and preserve kidney function. High blood pressure is a common and damaging effect of ADPKD. Half the

participants were assigned to a standard blood pressure group (between 120-130 over 70-80), and half to a lower blood pressure group (between 95-110 over 60-75) but still within the normal range.

Participants in the lower blood pressure group received more rigorous treatment, taking more medication to maintain a lower blood pressure. The lower blood pressure group had a 14 percent decrease in kidney cyst size compared to those in the standard blood pressure group. However, kidney function - measured by estimated glomerular filtration rate (eGFR) - was about the same as the standard group at the end of the trial, yielding no clinical benefit. About 15 percent more of the people in the lower blood pressure group experienced lightheadedness and dizziness.

"The HALT-PKD studies were well performed and the largest of their kind," said Robert Star, M.D., director of the Division of Kidney, Urologic, and Hematologic Diseases within NIDDK. "More research is needed to better understand how polycystic kidney disease destroys kidney function over time, and what combination of medications can most safely and effectively prevent or undo the damage caused by this devastating condition."

ADPKD is the most common kind of polycystic kidney disease, representing 90 percent of the approximately 600,000 U.S. cases. PKD is the fourth leading cause of kidney failure.

Provided by National Institute of Diabetes and Digestive and Kidney Diseases