



# PRESS RELEASE

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## High-Impact Clinical Trials Generate Promising Results for Improving Kidney Health: Part 1

**San Diego, CA (October 25, 2024)** — The results of numerous high-impact phase 3 clinical trials that could affect kidney-related medical care will be presented in-person at ASN Kidney Week 2024 October 23–27.

- Finerenone—a selective non-steroidal mineralocorticoid receptor antagonist—has been shown to have kidney protective effects in individuals with chronic kidney disease (CKD) with type 2 diabetes, but its effects on kidney outcomes in patients with heart failure with and without diabetes and/or CKD are not known. To investigate, researchers analyzed data from 6,001 participants enrolled in the FINEARTS-HF trial, a global, randomized clinical trial of finerenone versus placebo in patients with heart failure with mildly reduced or preserved ejection fraction (pump function). “We observed that, although finerenone led to an initial decline in kidney function measurements, longer-term kidney function patterns were similar to those receiving placebo,” said corresponding author Finnian R. Mc Causland, MBBCh, of Brigham and Women’s Hospital. “We also noted that finerenone reduced the amount of protein leaked by the kidneys, which is thought to be predictive of better patient outcomes.”

*Finerenone and Kidney Outcomes in Patients with Heart Failure: The FINEARTS-HF Trial*

- A multi-center randomized clinical trial including 4,003 hospitalized patients with acute kidney injury (AKI) assessed if rapid and remote diagnostic and therapeutic recommendations sent from a team of physicians and pharmacists to patient providers through the electronic health record prevent outcomes such as worsening of kidney injury, needing dialysis, and death. “We found that the intervention significantly improved several clinician behaviors regarding the management of AKI but did not reduce the primary outcome of developing worsening kidney injury, needing dialysis, or death,” said first author Abinet M. Aklilu, MD, MPH, of Yale University School of Medicine. “In future studies, we plan to assess if recommendations targeting individuals at high risk for severe kidney injury and specific phenotypes of kidney injury lead to improved outcomes.”

*Personalized Recommendations for AKI Using a Kidney Action Team: A Multicenter Randomized Controlled*

- Semaglutide (Ozempic) is a glucagon-like peptide 1 receptor agonist that has been shown to reduce albuminuria (a marker of kidney damage) and the risk of kidney failure in individuals with type 2 diabetes and CKD. In a new trial, researchers assessed the effects of semaglutide in patients with overweight/obesity and albuminuric CKD without diabetes. For the trial, 101 patients were randomized to semaglutide or placebo. At week 24, the placebo-corrected geometric average change in the urine albumin-to-creatinine ratio in patients taking semaglutide was -52.1%. Semaglutide compared with placebo changed body weight by -9.1 kg and systolic blood pressure by -6.3 mmHg. Gastrointestinal adverse events were more often reported in the semaglutide group compared with the placebo group. "In this investigator initiated clinical study, we assessed whether the body weight-lowering drug semaglutide can also protect the kidney in patients with CKD. We found that 6 months' treatment with semaglutide at 2.4 mg/week reduced albuminuria, improved blood pressure control, reduced body weight and body circumference in patients with CKD and obesity," said corresponding author Hiddo J.L. Heerspink, PhD, PharmD, of University Medical Center Groningen, in The Netherlands. "Future studies are needed to assess the long-term efficacy and safety of semaglutide in reducing the risk of kidney failure in these patients."

*Effects of Semaglutide on Kidney Parameters in Patients with Obesity and Nondiabetic CKD*

- Both tacrolimus and mycophenolate mofetil are immunosuppressive drugs recommended for children with frequently relapsing nephrotic syndrome and steroid-dependent nephrotic syndrome. A 243-patient multicenter, randomized, open-label, controlled trial compared the efficacy and safety of these 2 treatment options. Compared with mycophenolate mofetil, tacrolimus reduced the risk of relapse by 65%. Among patients who experienced relapse, the median time to first relapse was 225.5 days in the tacrolimus group and 165.5 days in the mycophenolate mofetil group. The tacrolimus group had fewer annual relapses and a reduced need for steroids than the mycophenolate mofetil group "We found that a 1-year course of tacrolimus therapy significantly extended the period of relapse-free survival in comparison with mycophenolate mofetil treatment. We are planning to evaluate the long-term efficacy and safety profile of tacrolimus in these patients," said first author Fei Liu, associate chief physician at The Children's Hospital, Zhejiang University School of Medicine, in China.

*Efficacy and Safety of Tac or MMF for Children with Steroid-Sensitive but Frequent Relapse or Steroid-Dependent Nephrotic Syndrome: A Nationwide, Multicentre Randomized Study*

- The EMPA-KIDNEY trial in patients with CKD showed that taking the sodium-glucose co-transporter 2 (SGLT2) inhibitor empagliflozin over 2 years safely reduced the trial's primary outcome of kidney disease progression or cardiovascular death by 28%. After completion of the active trial, 4,891 surviving participants have now been observed post-trial for a median of 2 additional years, revealing important residual cardiorenal benefits after the study drug was discontinued. "The carry-over effect was a 13% reduction in risk for the primary outcome, less than the 28% reduction whilst taking empagliflozin during the active trial, and appeared to last for only approximately 12 months, so maximizing benefits of SGLT2 inhibitors in CKD requires long-term treatment," said corresponding author Will Herrington, MBBS, MD, of the University of Oxford, in the UK..

*Long-Term Effects of Empagliflozin in CKD*

- CKD-associated pruritus, or itching, is a common and distressing condition that affects approximately 80% of patients with kidney failure who are on hemodialysis. The kappa opioid receptor is a promising target for treating itch because it plays a role in controlling itch neurotransmission. In a randomized trial of 545 patients undergoing hemodialysis who had moderate-to-severe pruritus, researchers tested the potential of HSK21542, a newly developed peripheral selective agonist of kappa opioid receptors. Intravenous HSK21542 treatment caused a significant lessening in itch intensity, with 51.0% of patients in the HSK21542 group experiencing a reduction of at least 3 points in the 0–10 Worst Itching Intensity Numerical Rating Scale at week 12, compared with 24.2% in the placebo group. "HSK21542 was generally safe and well-tolerated throughout the trial. Thus, HSK21542 will be launched in China in May of next year," said corresponding author Bi-Cheung Liu, MD, PhD, of Zhong Da Hospital Southeast University.

*Efficacy and Safety of HSK21542 for Moderate-to-Severe CKD-Associated Pruritus: A Phase 3 Trial in Hemodialysis Patients*

*Join ASN and approximately 12,000 other kidney professionals from across the globe at Kidney Week 2024 in San Diego, CA. The world's premier nephrology meeting, Kidney Week, provides participants with exciting and challenging opportunities to exchange knowledge, learn the latest scientific and medical advances, and listen to engaging and provocative discussions with leading experts in the field. Early programs begin on October 23, followed by the Annual Meeting from October 24-27. Follow the conversation at #KidneyWk.*

#### **About ASN**

*Since 1966, ASN has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge and advocating for the highest quality care for patients. ASN has nearly 21,000 members corresponding 140 countries. For more information, visit [www.asn-online.org](http://www.asn-online.org) and follow us on [Facebook](#), [X](#), [LinkedIn](#), and [Instagram](#).*

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