



PRESS RELEASE

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HIGH-IMPACT CLINICAL TRIALS YIELD RESULTS THAT COULD IMPROVE KIDNEY CARE

Washington, DC (October 23, 2020) — The results of numerous high-impact clinical trials that could affect kidney-related medical care will be presented online during ASN Kidney Week 2020 Reimagined October 19–October 25.

- Mineralocorticoid receptor overactivation may drive progression of chronic kidney disease through inflammatory and fibrotic processes. In a randomized, phase 3, placebo-controlled trial including 5,734 patients with chronic kidney disease and type 2 diabetes, investigators tested the efficacy and safety of finerenone, a novel mineralocorticoid receptor inhibitor. Compared with placebo, finerenone significantly reduced the risk of developing kidney failure or cardiovascular problems, and it was well-tolerated. “The FIDELIO-DKD trial is the first to demonstrate that a novel mineralocorticoid receptor blocker, different from traditional agents in the class, slows diabetic kidney disease progression and reduces cardiovascular events when added to standard of care. Additionally, this added benefit is with minimal risk of elevating serum potassium, a problem commonly seen with other agents in the class,” said lead author George L. Bakris, MD, of the University of Chicago Medicine. *Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes*
- In an analysis of 3,730 patients with heart failure and a reduced ejection fraction (HF_{REF}) enrolled in the EMPEROR-Reduced trial, the diabetes medication empagliflozin lowered the risks of heart failure, cardiovascular death, and serious kidney problems; and slowed kidney function decline compared with placebo. These effects were seen regardless of the presence or absence of chronic kidney disease and across a broad spectrum of baseline kidney function. *EMPEROR-Reduced: Empagliflozin and Outcomes in Heart Failure and Chronic Kidney Disease*
- A cyclical corticosteroid-cyclophosphamide regimen is recommended for patients with primary membranous nephropathy at high risk of progression. In a randomized and open-label controlled trial, 86 patients with primary membranous nephropathy and persistent nephrotic syndrome were assigned to receive a 6-month cyclical treatment with corticosteroid and cyclophosphamide or sequential treatment with tacrolimus and rituximab. Compared with tacrolimus-rituximab, corticosteroid-

cyclophosphamide induced remission of nephrotic syndrome at 24 months in a significantly greater number of patients. "In the STARMEN study, treatment with corticosteroid-cyclophosphamide was more effective (84%) than treatment with tacrolimus and rituximab (55%) in primary membranous nephropathy," stated lead author Gema Fernández Juárez, MD, of Hospital Universitario Fundacion Alcorcón, in Spain.

Sequential Treatment with Tacrolimus and Rituximab versus alternating Corticosteroids and Cyclophosphamide in Primary Membranous Nephropathy (PMN)

- Vadadustat (VADA) is an investigational, oral, hypoxia-inducible factor prolyl hydroxylase inhibitor being tested for the treatment of anemia in patients with chronic kidney disease. Researchers conducted 2 randomized, phase 3, global, open-label, sponsor-blind, parallel-group, active-controlled trials comparing oral daily VADA to parenteral darbepoetin alfa (DA) in patients with anemia and CKD who are not on dialysis (PRO₂TECT program). In total, 1,751 patients were randomized. Results will be presented at the meeting.

Global Phase 3 Clinical Trials of Vadadustat vs Darbepoetin Alfa for Treatment of Anemia in Patients with Non–Dialysis-Dependent Chronic Kidney Disease

- Hemodialysis is an intensive procedure that puts stress on patients who need it to survive. For patients with poor nutrition, eating protein during dialysis appears to improve their survival, but whether oral protein supplements can also help patients with better nutritional status is unknown. The Health Effects of Oral Protein Supplements in HD (HELPS-HD) Trial of 10,043 patients undergoing hemodialysis compared nutritional supplementation only when patients had poor nutritional status, indicated by low blood levels of albumin, the most abundant protein in blood, (the standard protocol), vs. nutritional supplementation regardless of blood albumin levels (the intensive protocol). Mortality rates were similar in the 2 groups: over a median follow-up of 21 months, there were 3,628 deaths, 35.8% in the intensive and 36.5% in the standard group. The rate of death was approximately 20 per 100 people over 1 year in both groups. "The findings suggest that giving protein supplements at dialysis to hemodialysis patients with more normal nutritional status does not lower the risk of death in hemodialysis patients," said lead author Daniel E. Weiner, MD, of Tufts Medical Center.

Oral Intradialytic Nutritional Supplements and Mortality in Hemodialysis Patients: a Cluster-Randomized, Pragmatic Clinical Trial

- Use of central venous hemodialysis catheters can lead to catheter-related blood stream infection (HD-CRBSI). The REDUCTION trial measured the rate of HD-CRBSI across Australia and tested the effect of a multifaceted, evidence-based intervention upon the rate of HD-CRBSI. After baseline data collection, clinics were randomly assigned to 1 of 3 time points (April 2018, Sept 2018, March 2019) for

implementation of an intervention package based upon current evidence and guidelines. Preliminary analyses showed that 5,246 catheters (3,506 patients) were inserted with central venous catheters during the baseline phase and 4,610 catheters (3,144 patients) in the intervention phase. The package of interventions did not appear to reduce infection rates, but the infection rate across the overall program fell further from an already low baseline rate, over time. "These results show the importance of using such robust study designs to understand the effect of complex intervention packages in real world settings and embedding clinical trials within routine practice," said lead author Martin P. Gallagher, MBBS, FRACP, MPH (Hons), PhD, of The George Institute for Global Health and the University of Sydney. "Data from this national study will allow a better understanding of the reasons for variation in patients' risk of such infections."

Reducing the burden of dialysis Catheter Complications: a National approach (REDUCCTION)

- For patients undergoing dialysis, some form of anticoagulation is typically administered at the time of dialysis to prevent blood clotting during the procedure. In a clinical trial of 638 critically ill patients with acute kidney injury receiving dialysis, anticoagulation with regional citrate (which provides anticoagulation within the dialysis circuit without increasing the risk of bleeding) resulted in significantly longer dialysis filter lifespan compared with systemic heparin anticoagulation.

Regional Citrate vs Systemic Heparin Anticoagulation During Continuous Kidney Replacement Therapy Among Critically Ill Patients with Acute Kidney Injury: A Randomized Clinical Trial

- The Dapagliflozin And Prevention of Adverse outcomes in Chronic Kidney Disease trial (DAPA-CKD) assessed the sodium glucose co-transporter 2 inhibitor dapagliflozin in patients with chronic kidney disease (CKD) with and without type 2 diabetes. In the trial, 4,304 patients were randomized to receive dapagliflozin 10mg once daily or placebo. "We found that the drug delayed patients starting dialysis, reduced cardiovascular events, and reduced the number of deaths. The drug worked as well in patients without diabetes as those with diabetes," said lead author David C. Wheeler, MD, of University College London. Dapagliflozin also provided benefits regardless of the underlying cause of CKD.

Effects of dapagliflozin on kidney function, cardiovascular events and all-cause mortality according to cause of kidney disease in the DAPA-CKD trial

ASN Kidney Week 2020 Reimagined, the largest nephrology meeting of its kind, will provide a forum for more than 13,000 professionals to discuss the latest findings in kidney health research and engage in educational sessions related to advances in the care of patients with kidney and related disorders. Kidney Week 2020 Reimagined will take place October 19–October 25.

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 more than 21,000 members representing 131 countries. For more information, visit www.asn-online.org.

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