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ASN KIDNEY WEEK 2014 NOVEMBER 11-16 PHILADELPHIA, PA

HIGH IMPACT CLINICAL TRIALS YIELD RESULTS THAT COULD LEAD TO IMPROVED KIDNEY CARE

Philadelphia, **PA (November 15, 2014)** — The results of numerous high-impact clinical trials that could affect kidney-related medical care will be presented at ASN Kidney Week 2014 November 11–16 at the Pennsylvania Convention Center in Philadelphia, PA.

- A trial of 156 patients who developed acute kidney injury (AKI) following cardiac surgery found that treatment with certain stem cells did not shorten the time it took patients to achieve complete kidney recovery, nor did it decrease their risk of dying prematurely or needing dialysis. Unfortunately, "AKI is common condition and there is no effective treatment," the researchers noted. ACT-AKI: A Phase 2 Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of AC607 for the Treatment of Acute Kidney Injury in Cardiac Surgery Subjects
- Follow-up of 8,494 patients in the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) trial, which is the largest clinical trial on diabetes, revealed that intensive glucose control leads to long-term reductions in the risk of developing end-stage kidney disease. "Our study also suggests that the benefits are greater when treatment is begun early in the course of the disease, and in people in whom blood pressure is well-controlled," said lead author Vlado Perkovic, MBBS, PhD, FRACP, FASN. "These results suggest that finding better ways to control glucose levels is key to preventing the epidemic of kidney failure due to type 2 diabetes around the world."

 ADVANCE-ON: long term benefits of intensive glucose control for end-stage kidney disease
- In a study of 558 patients with early autosomal dominant polycystic kidney disease (ADPKD), a leading cause of kidney failure, rigorous blood pressure control conferred benefits over standard blood pressure control related to a reduced rate of increase in total kidney volume and greater declines in measures of heart and kidney problems. "Hypertension was very well controlled in both treatment groups. The results emphasize the potential importance of early detection and aggressive treatment of hypertension in ADPKD," said lead author Arlene Chapman, MD. Also, in a study of 486 ADPKD patients with stage 3 chronic kidney disease, treatment

with an angiotensin-converting enzyme inhibitor (ACE-I) was safe and by itself sufficient to achieve blood pressure control in the majority of patients. "Both studies showed that ACE inhibitors alone or in combination with angiotensin receptor blockers are safe and well tolerated and achieve excellent blood pressure control in the majority of patients with ADPKD," said lead author Vincente Torres, MD, PhD. "However, both failed to demonstrate any superiority of dual blockade with an ACE inhibitor and an angiotensin receptor blocker compared to an ACE inhibitor alone." Hypertension in ADPKD develops early and associates with disease progression. —HALT Progression of Polycystic Kidney Disease (HALT PKD) Trials: Primary Results of a 2x2 Factorial Trial in Early Stage CKD —HALT Progression of Polycystic Kidney Disease Trials: Primary results of a randomized trial in moderately advanced stage CKD

- Among 200 patients on dialysis, extending weekly dialysis hours for 12 months did
 not improve quality of life, but was linked with improvements in some laboratory
 measures (such as potassium and phosphate blood levels) and a reduced need for
 blood pressure medications.
 Impact of Extended Weekly Hemodialysis Hours on Quality of Life and Clinical
 Outcomes: the ACTIVE Dialysis Multinational Trial
- Among 276 dialysis patients who were deficient in vitamin D, treatment with ergocalciferol (a vitamin D2 supplement) for 6 months normalized their circulating vitamin D levels. "Many hemodialysis patients are vitamin D deficient, and reports have extolled the health benefits of vitamin D administration," according to the investigators.
 Randomized Clinical Trial of Ergocalciferol Supplementation in 25 Vitamin D
- Among 416 patients with diabetic kidney disease, a drug that targets TGF-β1 (a protein thought to play a role in the disease) was safe but did not slow kidney function loss.
 Renal Efficacy and Safety of Anti-TGF-β1 Therapy in Patients with Diabetic Nephropathy

Deficient Hemodialysis Patients

• In a study of 265 dialysis patients, the Fluency® Plus Endovascular Stent Graft, which is placed inside a blocked stent to re-open it and allow adequate blood to flow and dialysis to take place, was superior to balloon angioplasty alone through 6 months. Therefore, use of the Fluency® Plus Endovascular Stent Graft is better for restoring blood flow and keeping the area open longer. "In-stent restenosis is a common problem in the care of end-stage renal disease patients. This study represents the first level-1 evidence for the use of stent-grafts in the treatment of both arteriovenous fistula and arteriovenous graft stenosis," said lead author Alexander Yevzlin, MD (University of Wisconsin).

Six-Month Results of the RESCUE Trial: Fluency® Plus Endovascular Stent Graft versus PTA for In-stent Restenosis

- In a substudy of the PeriOperative ISchemic Evaluation-2 (POISE-2) Trial that included 6,905 patients undergoing non-cardiac surgery, the use of aspirin around the time of surgery increased the risk of major bleeding, which was associated with a greater risk of subsequent AKI. The use of clonidine (a medication used to treat hypertension) around the time of surgery increased the risk of low blood pressure, which was associated with a greater risk of subsequent AKI. Compared with placebo, neither aspirin nor clonidine altered the risk of most AKI observed after major non-cardiac surgery. "Approximately 200 million adults undergo major non-cardiac surgery each year, and amongst patients taking aspirin prior to surgery there is substantial practice variability as to whether it is held or not in the perioperative period," the study investigators noted.
 - -The Effect of Perioperative Aspirin on Acute Kidney Injury (AKI)
 - -The Effect of Perioperative Clonidine on Acute Kidney Injury (AKI)

Disclosure information is available at http://www.asn-online.org/education/kidneyweek/2014/program-faculty.aspx.

ASN Kidney Week 2014, the largest nephrology meeting of its kind, will provide a forum for more than 13,000 professionals to discuss the latest findings in renal research and engage in educational sessions related to advances in the care of patients with kidney and related disorders. Kidney Week 2014 will take place November 11–16, 2014, in Philadelphia, PA.

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