Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/clinical-practice/nephrology/finerenone-vs-placebo-in-type-1-diabetes-and-ckd-updates-from-the-phase-3-fine-one-trial-from-the-kidney-meeting-2025-in-houston/36517/

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Finerenone vs Placebo in Type 1 Diabetes and CKD: Updates From the Phase 3 FINE-ONE Trial From the Kidney Meeting 2025 in Houston

Announcer:
Welcome to DataPulse from ASN Kidney Week 2025 on ReachMD. This activity, titled “Finerenone vs Placebo in Type 1 Diabetes and Chronic Kidney Disease: Updates From the Phase 3 FINE-ONE Trial From the Kidney Meeting 2025 in Houston” is provided by Medcon International.

Dr. Heerspink:
Hello, everyone. This is Hiddo Heerspink from the University of Groningen in the Netherlands. I'm here at ASN Kidney Week 2025 in Houston, where we presented yesterday the results of the FINE-ONE trial. It's my great pleasure to discuss these results in this session.

FINE-ONE was a randomized, double-blind, placebo-controlled trial in adults with type 1 diabetes and chronic kidney disease. Patients with a GFR between 25 and 90 and a urinary albumin-to-creatinine ratio between 200 and 5,000 mg/g creatinine who were already using standard of care, including ACE inhibitors or angiotensin receptor blockers, were randomly assigned to finerenone or placebo and were treated for 6 months. They then proceeded into a 1-month washout period.

The trial was a global clinical trial conducted in Asia, Europe, and North America. The primary outcome of the trial was the change from baseline in the urinary albumin-to-creatinine ratio. The secondary outcome was safety.

And you may wonder why we chose the urinary albumin-to-creatinine ratio as the primary outcome. In people with type 1 diabetes and chronic kidney disease, established kidney outcome trials, such as assessing the effect of the drug on dialysis or kidney transplantation, it’s very difficult because you require 5,000, 6,000 patients, and that is not feasible in type 1 diabetes and chronic kidney disease.

So instead, we used the change in albuminuria as a bridging biomarker to translate the already existing evidence for kidney protection with finerenone in type 2 diabetes to type 1 diabetes. So we use albuminuria as a bridge between type 2 diabetes and type 1 diabetes.

The trial enrolled 242 participants; 120 were randomized to finerenone; 122 were randomized to placebo. The mean eGFR at baseline was 59 mL/min, and the median urinary albumin-to-creatinine ratio 550 mg/g creatinine. The mean duration of diabetes was 32 years, and the mean age of these participants was 51 years. Nearly all participants were using an ACE inhibitor or angiotensin receptor blocker.

After 6 months of treatment, albuminuria was reduced in the placebo group by 13%. In the finerenone group it was reduced by 28%, and that was a statistically significant difference.

Now, the primary outcome was the change in albuminuria over the 6 months of treatment, and we had more visits over time where we measured urinary albumin-to-creatinine ratio. So the primary outcome—the change in albuminuria over 6 months—was reduced with finerenone by 25% compared to placebo, which, again, was highly statistically significant.

Finerenone in this population was well tolerated. The proportion of patients with an adverse event was similar between the finerenone

and placebo groups. Also, when we assessed serious adverse events, we found no difference between the 2 treatments.

There was an increase in hyperkalemia; 12 patients in the finerenone group, or 10%, reported hyperkalemia, versus 4, or 3.3%, in the placebo group. But importantly, the clinical impact of these adverse events was low, because very few led to treatment discontinuation, very few led to hospitalization, and none led to death.

Finerenone in this population also acutely reduced GFR, which is a phenomenon that we have seen in type 2 diabetes as well. It does not reflect kidney damage; it reflects the mode of action, because finerenone reduces the intraglomerular pressure. This effect was reversible when we discontinued the medication.

So overall, we demonstrated for the first time in 35 years that a new drug can benefit patients with type 1 diabetes. Finerenone reduced albuminuria by 25%. It was safe and well tolerated, except for hyperkalemia, but as I said, the clinical impact was low. So now we have a new therapy with a proven benefit-risk ratio for people with type 1 diabetes and chronic kidney disease that will likely translate into long-term kidney outcomes. So we were very pleased with these results, and we were very happy that we could present this data yesterday here at ASN Kidney Week.

So this was Hiddo Heerspink from the University of Groningen here at ASN Kidney Week. Thank you for listening, and I hope you will find this data useful for your clinical practice.

Announcer:
Thank you for listening to this DataPulse from ASN Kidney Week 2025 on ReachMD. This activity is provided by Medcon International. Thank you for listening.