PERFORMANCE Trial

NCT02975505

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Statistical Analysis

Safety outcomes, or rates of adverse events, will be tallied using simple proportions and descriptive statistics. Intention-to-treat analysis will be performed. Stratified analyses by diabetes status will be performed given the lack of robust trial data to support intensive BP lowering in patients with diabetes. We will also test for differences in the composite rates of hospitalizations, emergency room visits, and hyperkalemia in the two arms. We will explore differences in the rates of ESKD or cardiovascular events and determine if there is any effect modification of the intervention by level of proteinuria or by diabetes. For patients lost to followup, we plan to use chained multiple imputation to perform analyses.

Sample Size Rationale

We estimate that randomly assigning 90 participants to intensive versus less intensive SBP control would provide 80% power (with 2-sided α of 0.05) to detect a 6-mmHg difference in SBP (with SD of the change in SBP within each arm to be 10 mmHg) between the two arms at month 12. Anticipating approximately a 20% dropout rate given the pill burden and 10% loss to follow-up rate given the traditional known challenges in recruiting and retaining patients with advanced CKD to an interventional trial, we planned to enroll up to 120 participants