

Efficacy of Diuretics in Kidney Disease

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Data Analysis Plans

Data will be presented as mean and standard deviation. The effect of metolazone versus placebo on urine production (primary outcome) will be compared using the paired t-test. The effect of metolazone versus placebo on kidney clearance of uremic solutes, weight, and blood pressure will be compared using the paired t-test.

Rationale for Sample Size

Preliminary data of prevalent hemodialysis patients showed that among 33 patients on low-dose or no diuretic, the average urine output was 795 ± 556 mL/day. Based on this finding, 33 patients would provide 80% power and 43 patients would provide 90% power to test whether diuretic increases the primary outcome of urine production by 50%. To account for an estimated dropout rate of 20%, enrollment of 50 patients will be targeted to yield 40 patients completing the study.