

Efficacy of Twice Weekly Hemodialysis in Patients With Residual Kidney Function

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Data Analysis Plans

The prespecified primary outcome is the quality of life assessed by the KDQOL-36. Secondary outcomes are symptom burden assessed by the Dialysis Symptom Index, cognition assessed by the Trails Making B Test and Digit Substitution Test, and plasma solute levels. Equivalence between twice weekly and thrice weekly hemodialysis will be assessed based on the KDQOL-36 score using a mixed-effects model with a random intercept to take into account the repeated measures per patient. Treatment-by-period effect will be first tested by adding a treatment-by-period interaction; if nonsignificant, the treatment effect will be estimated with period and treatment as the covariates, and if significant, the treatment effect will be estimated using a linear regression model with data from the first period only. A two-sided 90% confidence interval (CI) will be calculated and equivalence concluded if the CI is contained within the prespecified margin of -5 and 5 for the KDQOL-36 score. For analysis of other outcomes, we will compare means using a mixed-effects model and medians using quantile regression with robust standard errors to account for the multiple observations per patient. The mixed-effects model assumed data to be missing at random while quantile regression assumed data to be completely missing at random. All analysis assumed 5% significance.

Rationale for Sample Size

The power calculation was based on a previous study in which repeat measures of the KDQOL-36 score at six weeks in a group of control hemodialysis patients had a paired difference of 2.1 ± 5.7 compared to the original value. Based on this finding, 30 patients would provide more than 90% power to test whether twice weekly hemodialysis was equivalent to thrice weekly hemodialysis with the equivalence margin defined as -5 and 5. The equivalence margin (γ) was chosen based on previous studies showing no association with adverse outcomes with this degree of reduction.