

A RANDOMIZED, PARALLEL, OPEN-LABEL STUDY TO COMPARE SEVELAMER CARBONATE POWDER DOSED ONCE PER DAY WITH SEVELAMER HYDROCHLORIDE TABLETS DOSED THREE TIMES PER DAY IN CHRONIC KIDNEY DISEASE PATIENTS ON HEMODIALYSIS

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Sevelamer carbonate powder (SCP; Renvela[®]) was developed as an alternative dosage form of sevelamer. SCP is mixed with water prior to use. This study explored the feasibility of SCP QD compared to sevelamer hydrochloride tablets (SHT) TID.

This was a randomized, parallel, open-label study in 217 HD patients. Following a 2-week phosphate binder washout to confirm serum P >5.5 mg/dL, patients were randomized (2:1) to SCP dosed QD with the largest meal or SHT dosed TID with meals for 24 weeks.

The mean actual dose was 6.9 g/day of SCP QD and 7.3 g/day of SHT TID. Mean serum P decreased 2.0 ± 1.8 mg/dL (from 7.3 ± 1.3 mg/dL) for SCP QD and 2.9 ± 1.3 mg/dL (from 7.6 ± 1.3 mg/dL) for SHT TID (both $p < 0.001$) following 24 weeks of treatment. The upper CI bound was 1.50 mg/dL. Therefore non-inferiority based on a margin of 1 mg/dL was not demonstrated. The target control ($P \geq 3.5 \leq 5.5$ mg/dL) response rate was 56% for SCP QD and 73% for SHT TID group. Results for CaxP product and lipids were similar to the serum P results. Overall, the percentage of patients with AEs was similar between treatment groups and consistent with the patients' underlying renal disease with the exception of treatment-related nausea (9% vs. 3%), vomiting (6% vs. 1%), and oral administration complication (4% vs. 0%) for SCP QD and SHT TID, respectively. A greater percentage of SCP QD patients discontinued due to these treatment related AEs, likely due to the total daily dose administered once daily.

Although less effective than SHT, SCP lowered serum P significantly, reaching KDOQI P target in a majority of patients.