

Efficacy and safety of sucroferric oxyhydroxide vs sevelamer carbonate in Chinese dialysis patients with hyperphosphataemia

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Background: Sucroferric oxyhydroxide (SFOH) is a non-calcium-based, oral iron-containing phosphate binder that has been demonstrated to be efficacious and generally well tolerated for the control of Serum Phosphorus (sP) in patients with chronic kidney disease undergoing dialysis. This study aimed to investigate the efficacy and safety of SFOH vs sevelamer carbonate in controlling sP in adult Chinese dialysis patients with hyperphosphataemia.

Methods: An open-label, randomized (1:1), active-controlled, parallel group, multicentre, phase III study of SFOH and sevelamer at starting doses of 1,500 mg/day and 2.4 g/day, respectively, was carried out in adult Chinese dialysis patients with hyperphosphataemia (sP >1.78 mmol/L) (NCT03644264). The primary efficacy endpoint was a non-inferiority analysis of change from baseline in sP at Week 12 (Last Observation Carried Forward [LOCF]) with SFOH vs sevelamer.

Results: 415 patients screened, 286 enrolled and randomized (142 to SFOH and 144 to sevelamer). Mean (Standard Deviation [SD]) baseline sP was 2.38 (0.57) and 2.38 (0.52) mmol/L, respectively. Mean (SD) change from baseline in sP at Week 12 (LOCF) was -0.71 (0.60) vs -0.63 (0.52) mmol/L, respectively [Figure 1], and difference (sevelamer minus SFOH) in least squares means (95% confidence interval [CI]) was 0.08 mmol/L (-0.02; 0.18) with the lower limit of the 95% CI above the non-inferiority margin of -0.34 mmol/L. SFOH reduced sP from baseline earlier (mean [SD] change from baseline -0.69 [0.55] vs -0.37 [0.47] mmol/L at Week 4, respectively) and with a lower pill burden (mean 3.2 vs 6.3 tablets/day over 12 weeks, respectively) than sevelamer. Safety and tolerability of SFOH were generally comparable to sevelamer and no new safety signals were observed for SFOH.

Conclusion: SFOH reduced sP from baseline and was non-inferior to sevelamer after 12 weeks of treatment in Chinese patients on dialysis with hyperphosphataemia. SFOH is an appropriate treatment option for these patients.