294

Effectiveness of Sodium Zirconium Cyclosilicate (SZC) in Haemodialysis Patients with Severe Hyperkalaemia in the DIALIZE Study

Dr Martin Ford[1], Professor Steven Fishbane[2], Dr Bruce Spinowitz[3], Professor Anjay Rastogi[4], Professor Nicholas Guzman[5], Dr Kieran McCafferty[6]

[1]King's College Hospital NHS Trust, London, United Kingdom, [2]Zucker School of Medicine at Hofstra/Northwell, New York, United States of America, [3]New York-Presbyterian Queens, New York, United States of America, [4]David Geffen School of Medicine, Los Angeles, United States of America, [5]AstraZeneca, Gaithersburg, United States of America, [6]Barts Health NHS Trust, London, United Kingdom

Background and Aims: Patients with severe hyperkalaemia require urgent intervention to avoid serious adverse outcomes and mortality. The phase 3b DIALIZE study (NCT03303521) showed that sodium zirconium cyclosilicate (SZC) reduces predialysis serum potassium (sK+) after the long interdialytic interval and is well tolerated in haemodialysis patients with hyperkalaemia. This post-hoc analysis of the DIALIZE data assessed the efficacy of SZC in patients with severe hyperkalaemia (defined as sK+ ≥6.0 mmol/L) at baseline.

Methods: The DIALIZE study randomised 196 patients 1:1 to placebo (n=99) or SZC (n=97). The study consisted of an 8-week treatment period, comprising a 4-week SZC dose titration phase followed by a 4-week evaluation phase. The starting dose of SZC was 5 g orally once daily on non-dialysis days (4 days/week) for the 4-week dose titration phase (titrated in 5 g increments to a maximum of 15 g on non-dialysis days) to achieve predialysis sK+ 4.0–5.0 mmol/L. Patients maintained a stable dose of SZC for the 4-week evaluation phase (SZC 5, 10 or 15 g). Here, treatment response was defined as achievement of predialysis sK+ of 4.0–5.5 mmol/L during ≥3 of 4 haemodialysis treatments after the long interdialytic interval during the 4-week evaluation phase and not requiring potassium-lowering rescue therapy. Rates of response were compared between those patients with and without baseline severe hyperkalaemia (sK+ ≥6 mmol/L and <6 mmol/L, respectively). The sK+ measurement on Visit 1 (Day –7) was used as the baseline value.

Results: At baseline, 88 patients had sK+ ≥6 mmol/L (SZC n=46, placebo n=42) and 106 patients had sK+ <6 mmol/L (SZC n=49, placebo n=57); data were missing for two SZC patients. The overall proportion of treatment responders (irrespective of treatment and dose) in patients with baseline sK+ ≥6 mmol/L and <6 mmol/L was 44.3% and 43.4%, respectively. The proportion of treatment responders was greater with SZC compared with placebo in patients with baseline sK+ ≥6 mmol/L and sK+ <6 mmol/L (Figure). For patients receiving SZC, the proportion of treatment responders was consistent in those with baseline sK+ ≥6 mmol/L (67.4%) compared with those with baseline sK+ <6 mmol/L (71.4%; Figure).

Conclusion: Our results suggest that SZC is effective in haemodialysis patients with severe hyperkalaemia.