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Comparison Of Evocalcet With Cinacalcet In East Asian Patients With Severe Secondary Hyperparathyroidism Undergoing Hemodialysis: A Post-Hoc Analysis Of ORCHESTRA Study

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Objectives : The ORCHESTRA study showed that evocalcet was non-inferior to cinacalcet when orally administered once daily for 52 weeks in East Asian patients with secondary hyperparathyroidism (SHPT) receiving hemodialysis. We conducted a post-hoc analysis to investigate outcomes in the subgroup of ORCHESTRA study subjects with severe SHPT (>500 pg/mL) at inclusion.
Methods : This post hoc analysis used data of patients with severe SHPT in the ORCHESTRA trial, a randomized, double-blind, parallel-group study comparing evocalcet with cinacalcet. The primary endpoint was mean percent change in intact parathyroid hormone (iPTH) level from baseline in the evaluation period (weeks 50 to 52) and the percent ratio to baseline in intact PTH level at week 20, week 40 and last visit. The primary efficacy variable was analyzed by descriptive statistics and 95% CI for mean of percent change values; percent ratio to baseline at last visit was compared between evocalcet and cinacalcet with t-test and analyzed the trajectories of each group parameter using a repeated measures ANCOVA model.
Results : A total of 146 patients were included in evocalcet arm and 131 in the cinacalcet arm (52.7% and 47.3% of the study population, respectively). Mean patient age was 51.5 and 50.9 years, and mean baseline iPTH, 924.05 pg/mL and 1022.84 pg/mL, respectively. The percent ratio of intact PTH level reduction compared with baseline was statistically significant (table 1). Also, the weekly iPTH level curves of evocalcet and cinacalcet started to separate from week 32 onwards (Figure 1).The incidence of upper gastrointestinal tract related ADRs was lower in the evocalcet group (29.9%) than the cinacalcet group (50%).
Conclusions : Notwithstanding the limitations of post hoc analysis, these results demonstrate increased efficacy and safety of evocalcet in the treatment of hemodialysis patients with severe SHPT, as compared with cinacalcet.

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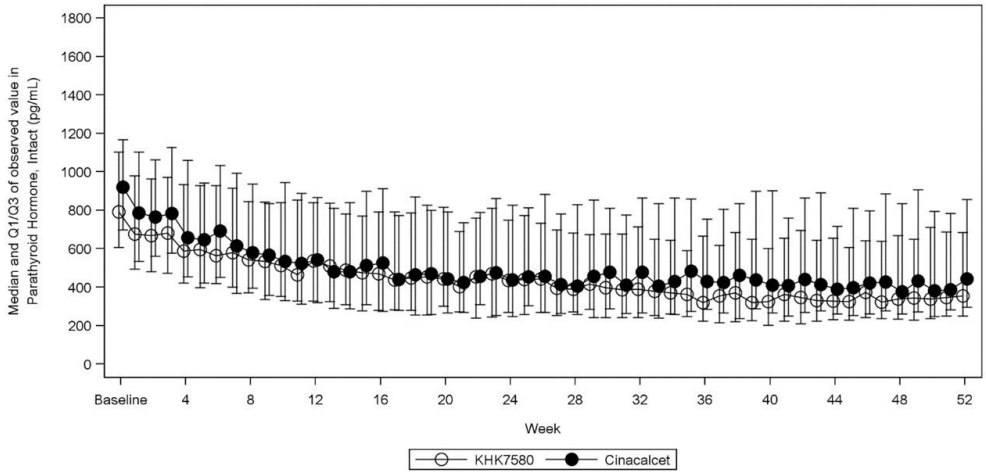

Figure 1. Intact PTH level over time in patients with severe SHPT at baseline

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Parameter			Evocalcet N = 146	Cinacalcet N = 131
		n	123	113
Factor[$]	Treatment group	p-value	0.5956	
	Primary disease	p-value	0.6319	
	Duration of dialysis	p-value	0.5540	
	Baseline value	p-value	0.2811	
	Visit	p-value	0.2484	
	Visit * Treatment group	p-value *2	<.0001	
	Visit * Primary disease	p-value	0.5225	
	Visit * Duration of dialysis	p-value	0.4523	
	Visit * Baseline value	p-value	0.0700	
Visit	Week 20	LS Mean[95%CI]	67.20 [59.33, 75.07]	58.24 [50.33, 66.16]
	Week 40	LS Mean[95%CI]	52.10 [43.69, 60.50]	61.70 [53.24, 70.15]
	Last visit *1	LS Mean[95%CI]	55.59 [47.25, 63.93]	61.59 [53.19, 69.98]
		Treatment Difference[95%CI]	-6.00 [-15.83, 3.84]	
		p-value	0.2312	

[$]Analyzed the trajectories of each group parameter using a repeated measures ANCOVA model with factors for treatment group, primary disease ("Chronic glomerulonephritis", "Diabetic nephropathy", "Others"), duration of dialysis ("< 10 years", ">= 10 years"), intact PTH value at baseline and visit (Week 20, Week 40, Last visit)

Least square (LS) Mean, confidence intervals (CI) are based on repeated measures ANCOVA model of the percent ratio to baseline in intact PTH, with factors for treatment group, primary disease ("Chronic glomerulonephritis", "Diabetic nephropathy", "Others"), duration of dialysis ("< 10 years", ">= 10 years"), intact PTH value at baseline and visit (Week 20, Week 40, Last visit)

Percent ratio to baseline: 100 x (Observed value / Baseline value)

Treatment Difference: Evocalcet - Cinacalcet

*1 After week 40

*2 Significance level of 0.2, testing for heterogeneity (interaction between visit and treatment)

Table 1. Summary of percent ratio to baseline in intact PTH assessed by repeated measures ANCOVA model (Full analysis set with severe SHPT patients)