

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE SAFETY AND EFFICACY OF DOXERCALCIFEROL IN VITAMIN D-REPLETE CKD PATIENTS

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This study was designed to assess the safety and efficacy of doxercalciferol (DOX) in vitamin D-replete [$25(\text{OH})\text{D} \geq 30 \text{ ng/mL}$] Stage 3 and 4 CKD subjects with secondary hyperparathyroidism.

This was a randomized, double-blind, placebo-controlled, parallel study. During the Screening Period, subjects with $25(\text{OH})\text{D} < 30 \text{ ng/mL}$ were administered ergocalciferol to achieve a vitamin D-replete state. Twenty-four vitamin D replete (exogenous ergocalciferol or intrinsically replete) subjects with elevated iPTH were randomized to DOX or placebo (PBO) for 24 weeks.

Compared to PBO, a greater percentage of DOX subjects met the iPTH target range (Stage 3: $< 70 \text{ pg/mL}$; Stage 4: $< 110 \text{ pg/mL}$) at 1, 2 and 3 consecutive visits. All DOX subjects achieved a 30% reduction in iPTH at 1 study visit and compared to PBO, a greater percentage of DOX subjects achieved a 30% reduction at 2 and 3 consecutive visits.

	Placebo (N=12) n (%)	Doxercalciferol (N=12) n (%)
Meeting iPTH target range:		
At 1 visit	4 (33.3)	11 (91.7)
For 2 consecutive study visits	2 (16.7)	10 (83.3)
For 3 consecutive study visits	2 (16.7)	10 (83.3)
Achieving a 30% reduction:		
At 1 visit	9 (75.0)	12 (100.0)
For 2 consecutive study visits	3 (25.0)	11 (91.7)
For 3 consecutive study visits	1 (8.3)	11 (91.7)

DOX and PBO were well tolerated during the study. The nature of the adverse events was consistent with the administration of active vitamin D to CKD patients. There were no clinically meaningful changes from baseline to end of treatment in Ca, $25(\text{OH})\text{D}$ or $1,25-(\text{OH})_2\text{D}$.

In this study, DOX was well-tolerated and effective in reducing iPTH in vitamin D-replete Stage 3 and 4 CKD patients.