



2.0 Synopsis

This was a prospective, non-randomized, multi-center study to assess the efficacy and safety of intravenous or oral paricalcitol administered over 6 months to patients with secondary hyperparathyroidism on either peritoneal- or hemodialysis program. The study was originally designed as a cohort without control group, resembling habitual clinical practice.

Paricalcitol showed to be effective in reducing basal iPTH levels consistently through the 6-month follow-up. The patients in peritoneal dialysis program showed, who were receiving oral paricalcitol, showed a better efficacy profile, in both total iPTH levels and in the number of patients with cut-off values. This benefit can be shown as soon as the first follow-up visit and peaks at visit 3.

Episodes of hypercalcemia or hyperphosphatemia were frequent in this study. Nonetheless, the timing gap between laboratory diagnosis, paricalcitol dose adjustment and/or the addition of phosphorus binders may explain the rather high incidence of these adverse events. Moreover, dialysis solution used in Mexico contains higher calcium levels than other countries, and the impact of serum calcium could have been understated. No nutrition control was implemented, so maybe local lifestyles could have negatively influenced serum calcium levels.

Paricalcitol showed to be effective in both oral and intravenous administration in reducing basal iPTH values in patients with secondary hyperparathyroidism due to chronic kidney disease. Effects are observed as soon as the second visit and the number of patients with cut-off points constantly increase throughout the study. Nonetheless, the number of hyperphosphatemia cases may be above the expected rate. This is explained because some protocol deviations, mainly the delayed use of phosphorus binders and the incorrect timing of dose adjustment of study product.