

**Randomized controlled trial to compare the efficacy and safety of oral paricalcitol with oral calcitriol in dialysis patients with secondary hyperparathyroidism.**

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**Source**

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**Abstract**

**AIM:**

The objective of the study was to compare the efficacy and safety of oral paricalcitol with oral calcitriol for treating secondary hyperparathyroidism.

**METHODS:**

We conducted the first multicenter open-labelled parallel group randomized controlled trial in 66 patients on dialysis. Patients were randomized to paricalcitol or calcitriol at a 3:1 dose ratio and adjusted to maintain intact parathyroid hormone (iPTH) level between 150-300 pg/mL, serum calcium  $\leq 2.74$  mmol/L and calcium-phosphate product  $\leq 5.63$  mmol<sup>2</sup> /L<sup>2</sup> . The primary end point was the proportion of patients who achieved  $>30\%$  reduction in iPTH.

**RESULTS:**

At 24 weeks, 22 (61.1%) patients in the paricalcitol and 22 (73.3%) in the calcitriol group had achieved the primary end-point (P-value = 0.29). The cumulative proportion of patients who achieved the end-point at 6 weeks, 12 weeks and 24 weeks were 50%, 80.6% and 86.1%, respectively, in paricalcitol and 53.3%, 86.7% and 86.7%, respectively, in the calcitriol group (P-value = 0.67). Median time to the end-point was 6 weeks in both groups. There were no significant differences in iPTH level at any time during the study. The median reduction in iPTH at 24 weeks was 48.4% in the paricalcitol group and 41.9% in the calcitriol group (P-value = 0.6). The median maximal iPTH reduction was 77.1% (paricalcitol) and 83.7% (calcitriol), P-value = 0.3. Serum calcium and incidence of hypercalcaemia did not differ between groups. 16.7% of patients in both groups had at least one episode of hypercalcaemia (serum calcium  $>2.74$  mmol/L). Other adverse events were similar between groups.

**CONCLUSION:**

Our study suggests that oral paricalcitol has similar efficacy and safety to oral calcitriol.

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