

4.0 Abstract

Title: Post Marketing Observational Study to Assess Patient Management Practices and Quality of Life with the Capsules Form of Paricalcitol in the Treatment of SHPT in Stage 3 – 5 Chronic Kidney Disease Patients Not Yet on Dialysis Under Conditions of Usual Clinical Care (CAPITOL)
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Keywords: Paricalcitol; Renal insufficiency, chronic; Hyperparathyroidism, secondary; Observation; Prospective studies
Rationale and Background: Paricalcitol capsules (Zemplar®) received marketing authorization [REDACTED] in late 2007 for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal insufficiency (CKD Stages 3 and 4) patients and chronic renal failure (CKD Stage 5) patients on hemodialysis or peritoneal dialysis. Based on data from clinical trials paricalcitol should be a useful therapy in patients with secondary hyperparathyroidism associated with chronic renal insufficiency across the spectrum of CKD (Stage 3 – 5). Accordingly, additional data are desired to evaluate patient management practices and the treatment of bone and mineral metabolism abnormalities under conditions of usual clinical care [REDACTED].
Research Question and Objectives: The primary objective of this PMOS is to further characterize the prescribing habits and patient management practices of physicians prescribing paricalcitol capsules and to assess the metabolic safety and effectiveness of paricalcitol capsules for the treatment of SHPT in stage 3-5 CKD patients not yet on dialysis under conditions of usual clinical care.
Study Design: This open-label, multicenter post-marketing, observational study was to be conducted in accordance with the [REDACTED] for paricalcitol capsules. The data collection period for each individual patient was defined as the period from 6 months before the administration of the initial dose, the period from Day 1 of paricalcitol capsules, and continued up to 6 months after the administration of the initial dose of paricalcitol capsules. Data collection was to be performed at two occasions, inclusion and at 6 month follow-up or early termination. Retrospective laboratory data collection from 6 months before the administration of the initial dose was to be conducted at inclusion.
Setting: The data in this Post Marketing Observational Study was collected in Sweden. There were 10 centers included in the study. Data collection started on 01 February 2011 (First Patient In) and data collection ended on 08 November 2012 (Last Patient Out).
Subjects and Study Size: The number of patients to be enrolled was approximately 100 to 150. Approximately 10 sites were to be participating in the study. Planned enrollment for each site was approximately 10 patients. Planned: 100 – 150 patients Actual: 50 patients Analyzed: 49 patients

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Variables and Data Sources: Data was collected in an eCRF through an internet based system. Each study site received a unique log in for the data collection. The required data were entered into the eCRF using patient's medical records as source data. For the 6-month retrospective chart review, un-personified printouts of laboratory data from the patient's records were faxed to data management for manual input into the clinical study database. Only the patients study specific number identified the patient on these printouts. Two analysis data sets were to be used:

Full Analysis Set (FAS): All included subjects who received at least 1 dose of paricalcitol capsule.

Per-Protocol Analysis Set (PPAS): All included subjects who received at least 1 dose of paricalcitol capsule and had analyzable data for the primary endpoints, i.e. 5-8 months after inclusion (between 150 and 269 days).

The PPAS was to be considered the main analysis set for the primary analyses.

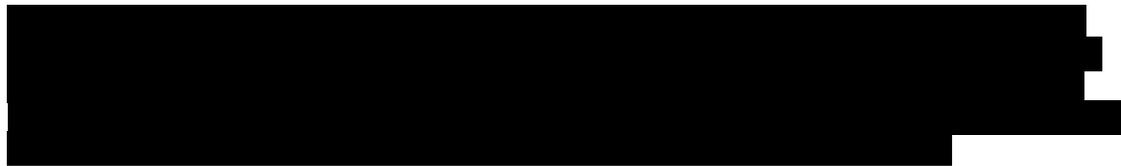
Results:

- IPTH decreased from baseline to 6 months. In PPAS the mean change in iPTH from baseline to 6 months was -6.2 pmol/L (95% confidence interval between -10.6 and -1.8). Similar results were found for the FAS population.
- There were 27.5% of the patients with iPTH within K/DOQI target at Final visit compared to 15.0% at Inclusion visit in the PPAS. Similar results were found for the FAS population.
- In the PPAS the proportion of patients with elevated s-Ca level was 42.5% at both Final visit and Inclusion visit. Twenty-five percent (25.0%) of the patients had elevated s-P level at Final visit compared to 15.0% of the patients at Inclusion visit. Similar results were found for the FAS population.

Discussion: Paricalcitol capsules improved iPTH but the changes were modest and not in parity with what have been shown in randomized clinical trials. There were minor changes in calcium and phosphate levels. No changes in quality-of-life as indicated by KDQOL-SF mean changes were noted on the physical and mental components. Mean weekly doses remained low and stable throughout the 6 months of observed treatment. Very few dose-titrations were made. Optimizing the treatment, especially with focus on dose titration, could potentially improve the clinical results. Paricalcitol remains an important SHPT treatment tool for the physicians.

Marketing Authorization Holder: AbbVie AB

Names and Affiliations of Principal Investigators:



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