복막투석 환자의 이차성 부갑상선 항진증 치료에서 cinacalcet 의 효능에 관한 연구

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Cinacalcet stUdy for Peritoneal Dialysis Patients In Double Arm on the Lowing Effect OF iPTH Level (CUPID) : Interim Report

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Cinacalcet, a novel calcimimetic, targets the calcium-sensing receptor to lower PTH levels in dialysis patients with secondary hyperparathyroidism (SHPT). However, the efficacy of cinacalcet in the peritoneal dialysis(PD) patients has not been demonstrated yet. This study compares the efficacy of a cinacalcet-based regimen with unrestricted conventional care (vitamin D and phosphate binders) for achieving the stringent NKF-KDOQI targets for PD patients.

This is a multicenter, open-label study. PD patients (N=85) with poorly controlled SHPT (iPTH >300 pg/mL) will be randomized 1:1 to receive either cinacalcet-based regimen or conventional care. Patients will be enrolled if they are >18 yr of age, had receive PD for >3 mo, intact PTH level >300 pg/mL, albumin corrected Ca level >9.0 mg/dL.

Subjects were randomly assigned to treatment with either cinacalcet and low-dose oral vitamin D or oral vitamin D alone to achieve KDOQI-recommended bone mineral targets (iPTH, Ca, P, Ca×P). For both groups, phosphate binders can be prescribed at the doctor's discretion. This study includes a 4-week screening (including vitamin D washout), a 12-week dose-titration, and an 4-week assessment phases.

Total sixty two patients were enrolled in the study so far. Among them, only the subjects (n=38) who finished 12-week dose titration period were analyzed in the interim analysis. No difference were exhibited in terms of age, gender ratio, height, weight, BMI, blood pressure, Kt/V, baseline PTH, corrected Ca, P, and Ca×P between treatment(n=18) and control(n=20) groups.

Cinacalcet group received 32.1 +/-18.2 mg of cinacalcet during titration period. Cinacalcet group achieved a trend toward higher achievement of >30% reduction in parathyroid hormone (iPTH) from baseline (66.7% vs 50 %, p=0.34) and higher achievement of PTH goal <300 pg/mL (33.3% vs 15.0%, p=0.26). Both groups showed similar achievement of targets for mean Ca×P (<55 mg^2/dL^2, 73.3% vs 62.5%), Ca (<9.5 mg/dL, 86.7% vs 56.2%), P (<5.5 mg/dL, 53.3% vs 68.8%). Corrected Ca level decreased mildly during cinacalcet therapy (from 9.8 +/-0.58 mg/dL to 9.2 +/- 0.7 mg/dL, p=0.01) but no symptomatic or severe hypocalcemia developed. Our interim analysis suggests that cinacalcet treatment when combined with oral active vitamin D therapy has a beneficial effect in achieving KDOQI targets for the treatment of SHPT in PD patients.

Key Words: 부갑상선항진증, PTH, 시나칼셋
Hyperparathyroidism, PTH, Cinacalcet