Endocrinología, Diabetes y Nutrición

362 - EFFICACY AND SAFETY OF WEEKLY CALCIFEDIOL 100 & 125 µG DOSES COMPARED TO PLACEBO IN SUBJECTS WITH SEVERE VITAMIN D DEFICIENCY

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Resumen

Introduction: Severe vitamin D deficiency increases the risk of fractures and contributes to osteoporosis, muscle weakness and impaired immune function. Calcifediol weekly-dose formulations may optimize vitamin D supplementation outcomes.

Objectives: To assess the efficacy and safety of weekly calcifediol 100 and 125 µg compared to placebo in patients with 25(OH)D levels # 20 ng/mL and/or ≥ 30 ng/mL at 16 weeks of treatment.

Methods: Phase II-III, double-blind, two-cohorts, randomized, controlled, multicenter study. In Cohort 2, presented here, subjects were randomized 2:2:1 to weekly calcifediol doses of 100, 125 µg or placebo, respectively, up to 52 weeks.

Results: 276 subjects with a mean age of 55.2 years (SD 15.42) were randomized. At week 16, response level of ≥ 20 ng/mL was achieved by most of the subjects receiving calcifediol 100 µg (92.3%) and 125 µg (91.8%) versus placebo (7.3%). Response level of ≥ 30 ng/mL was achieved by 49% and 76.4% of the subjects in calcifediol 100 mcg group and 125 µg group, respectively and none subjects in placebo group. Both calcifediol doses demonstrated superiority over placebo at each response level at all timepoints (p 80 ng/mL at week 52, with normal serum calcium (tCa) levels. Along the complete study, incidence of subjects with tCa levels > 10.5 mg/dL was low: 3 in placebo group and 2 in each of the calcifediol groups.

Conclusions: Long-term weekly administration of calcifediol 100 and 125 mcg has shown to be effective and safe for adults with severe vitamin D deficiency.