A Randomized Double-blinded Controlled Trial of Ergocalciferol 40,000 versus 100,000 IU/Week for Vitamin D Inadequacy in Institutionalized Postmenopausal Women

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Background: Vitamin D inadequacy constitutes a largely unrecognized problem in post-menopausal women. Previous study found that ergocalciferol 40,000 IU per week raises serum 25-hydroxyvitamin D level to normal level (>30 ng/mL) in only 60% of subjects. No study has examined the efficacy and safety of higher dose of ergocalciferol in treatment of vitamin D inadequacy in institutionalized postmenopausal women.

Objective: To evaluate the efficacy and safety of ergocalciferol 40,000 IU versus 100,000 IU per week for 12 weeks in treatment of vitamin D inadequacy in institutionalized postmenopausal women.

Methods: A randomized double-blind controlled trial was conducted in institutionalized postmenopausal women with vitamin D inadequacy. Ninety-four subjects were randomly assigned into two groups. Group A was given ergocalciferol 40,000 IU per week and group B was given ergocalciferol 100,000 IU per week for 12 weeks. Serum 25(OH)D level, calcium and phosphate, handgrip strength, timed up and go (TUG) test, and EQ-5D-5L were measured at baseline and 12 weeks after randomization.

Result: Of the 94 subjects enrolled, 85 subjects completed the study. At the end of the study, the increase of 25(OH)D level was significantly higher in group B than group A, with mean± standard deviation (SD) of 32.5±19.6 and 15.2±8.1 (p<0.001), respectively. More subjects in group B (90.9%) had normal 25(OH)D level than those in group A (65.9%), p=0.007. In a subgroup analyses of subjects with vitamin D deficiency, defined as 25(OH)D < 20 ng/mL (n=44), more subjects in group B (88.0%) had normal 25(OH)D level than subjects in group A (47.4%), p=0.007. In a subgroup analyses of subjects with severe vitamin D deficiency, defined as 25(OH)D < 10 ng/mL (n=9), more subjects in group B (100%) had normal 25(OH)D level than subjects in group A (16.7%), p=0.018. There were no differences in serum calcium, serum phosphate, handgrip strength, TUG and EQ-5D-5L between the two groups at baseline and 12 weeks after randomization.

Conclusion: Both ergocalciferol 40,000 and 100,000 IU per week for 12 weeks can increase 25(OH)D level. There were higher proportions of subjects who received ergocalciferol 100,000 IU per week achieving normal 25(OH)D level than those with 40,000 IU per week. In subjects with severe vitamin D deficiency, treatment with ergocalciferol 100,000 IU per week might be a better option to normalize 25(OH)D level with no differences in adverse events.

Keywords: Postmenopausal women, Ergocalciferol, Vitamin D inadequacy