

Publication

Vitamin D oral intermittent treatment (DO IT) study, a randomized clinical trial with individual loading regimen

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Comparison of several regimens of oral vitamin D including an individually calculated loading regimen with the aim of achieving serum values $> 75 \text{ nmol/l}$. Interventional, randomized, 3-arm study in vitamin D-deficient outpatients. Participants were allocated to supplementation of 24,000 IU vitamin D monthly over three months, using either a monthly drinking solution (Vi-De 3) or capsule (D; 3; VitaCaps), or an individualized loading regimen with the capsules taken weekly. For the loading regimen, the cumulative dose was calculated according to baseline 25-hydroxy-vitamin D (25(OH)D) serum value and body weight. Main inclusion criteria were age ≥ 18 years and 25(OH)D serum concentration $< 50 \text{ nmol/l}$. The primary outcome was 25(OH)D serum concentration one week after treatment termination. Secondary endpoints were patient's preferences and adverse events. Full datasets were obtained from 52 patients. Mean 25(OH)D values were statistically significant higher after a loading regimen compared to a monthly administration of 24,000 IU vitamin D (76.4 ± 15.8 vs $61.4 \pm 10.8 \text{ nmol/l}$; $p < 0.01$). All patients treated with the loading regimen reached sufficient 25(OH)D values $> 50 \text{ nmol/l}$. Serum 25(OH)D values $> 75 \text{ nmol/l}$ were observed more frequently in patients taking the loading regimen (47% vs 11% drinking solution vs 12% capsules). Vitamin D-related adverse effects did not occur in any treatment groups. Capsules were preferred by 88.5% of the patients. Compared to treatments with monthly intake of 24,000 IU vitamin D, the intake of an individually calculated weekly loading regimen was able to raise serum concentrations $> 50 \text{ nmol/l}$ in all cases within a safe range.

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