

## SHORT TERM AND LONG TERM SAFETY OF WEEKLY HIGH DOSE VITAMIN D<sub>3</sub> SUPPLEMENTATION IN SCHOOL CHILDREN

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**Short Title:** Short term and long term safety of Vitamin D in youth

**Key words:** safety, recommendations, daily allowance, hypovitaminosis D, children.

### Abstract

**Background:** Hypovitaminosis D is prevalent in youth worldwide, but the safety of vitamin D at doses exceeding 200 IU/day is unknown in this age group. We assessed the safety of high doses of vitamin D<sub>3</sub> administered to apparently healthy school children.

**Methods:** short term safety: 25 subjects randomly received placebo or vitamin D<sub>3</sub> at doses of 14,000 IU/wk for 8 weeks. Long term safety: 340 subjects randomly received placebo, vitamin D<sub>3</sub> as 1400 IU or 14,000 IU/week for one year. Biochemical variables were monitored at 0, 2, 4, 6, 8 weeks, and 8 weeks off therapy in the short term study and at 0, 6 and 12 months in the long term study.

**Results:** In both the short term and long term studies, mean serum calcium and 1,25-OHD levels did not change in any group. In the short term study, mean 25-OHD concentrations increased from 44 (± 11) ng/ml to 54 (± 19) ng/ml in the treated groups (P=0.033). In the long term study, mean 25-OHD levels increased from 15±8 to 19±7 ng/ml (p<0.0001) in subjects receiving 1400 IU/wk; and from 15±7 to 36±22ng/ml in the group receiving 14,000 IU/wk (p<0.0001). No subject developed vitamin D intoxication.

**Conclusion:** Vitamin D<sub>3</sub> at doses equivalent to 2,000 IU/day for one year is safe in adolescents and results in desirable vitamin D levels.