

Vital D Study (conducted through the Department of Clinical and Biomedical Sciences, Barwon Health, The University of Melbourne)

Sanders KM, Stuart AL, Williamson EJ, Simpson JA, Kotowicz MA, Young D, Nicholson GC. Annual high-dose oral vitamin D and falls and fractures in older women. A randomised controlled trial. *JAMA*. 2010;303(18):1815-1822.

Design A double-blind, placebo-controlled trial of 2,256 community-dwelling women, aged 70 years or older (median age 76 years), who were randomly assigned to receive oral cholecalciferol (vitamin D₃) 500,000IU or placebo each autumn to winter for three to five years.

Results Women in the vitamin D group had a 15% increased rate of falls ($p=0.025$) and a 26% increased rate of fractures ($p=0.047$), compared to those in the placebo group. The rate of falling in the vitamin D group was greatest in the first three months after dosing.

In a sub-study, the median baseline serum 25-hydroxycholecalciferol was 49nmol/L. Less than 3% of the sub-study participants were vitamin D deficient (ie 25-hydroxycholecalciferol levels <25nmol/L). In the vitamin D group, serum 25-hydroxycholecalciferol increased at one month post dosing to approximately 120nmol/L.

Conclusion Among older community dwelling women, annual oral administration of high dose vitamin D resulted in an increased risk of falls and fractures.

Comments in relation to the Vital D study:

- High dose supplementation is not recommended (a single 500,000IU loading dose in an older female population has been shown to increase falls and fractures)
- Vitamin D supplementation of 1000IU-2000IU per day in people with deficiency or at risk of deficiency is likely to be safe and beneficial.
- Up to 60,000IU per month may be safe, higher doses than this may not be
- In certain sub-groups of the population moderate doses may be justified
- When recommending vitamin D supplements, it would be prudent to aim for serum levels of 25-hydroxyvitamin D between 50 and 100nmol/L