

High-dose vitamin D linked with increased risk of falls, fractures among older women

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Women age 70 years or older who received a single annual high dose of vitamin D had a higher rate of falls and fractures compared to women who received placebo, according to a study in the May 12 issue of *JAMA*.

The results of studies investigating the effects of cholecalciferol (vitamin D) supplementation on falls and fractures have been inconsistent, with some meta-analyses indicating a reduced [fracture risk](#), while others have concluded that vitamin D supplementation is ineffective, or may increase the risk of fracture. For individuals attempting to modify their risk of falls or fractures via vitamin D, adherence to daily supplementation is typically poor, according to background information in the article.

Kerrie M. Sanders, Ph.D., of the University of Melbourne, Geelong, Australia and colleagues conducted a study to examine whether high-dose cholecalciferol (500,000 IU) given orally once a year to [older women](#) would reduce falls and fractures. The vitamin D was given in a single, high-dose to address low adherence and to be a practical intervention easily translated to clinical practice. The trial included 2,256 community-dwelling women, ages 70 years or older, considered to be at high risk of fracture, who were recruited from June 2003 to June 2005 and were randomly assigned to receive 500,000 IU of cholecalciferol or placebo each autumn to winter for 3 to 5 years. The study concluded in 2008.

The trial participants had a total of 5,404 falls over the study period, with 74 percent of 837 women in the vitamin D group and 68 percent of 769 women in the placebo group having at least 1 fall. Analysis indicated women in the annual high-dose vitamin D group experienced 15 percent more falls. Women in the vitamin D group had 171 fractures vs. 135 in the placebo group, with 26 percent more fractures for participants in the vitamin D group, who also had a 31 percent higher incidence of falls in the first 3 months following dosing.

"This is the first study to demonstrate increased risk of falls associated with any vitamin D intervention and the second study to demonstrate an increased fracture risk associated with annual high-dose vitamin D therapy in elderly [women](#). Our study used the largest total annual dose of vitamin D (500,000 IU) reported in any large randomized controlled trial, raising the possibility that the adverse outcome is dose-related. The opposing outcomes of 2 studies that used the same total annual dose (300,000 IU intramuscularly) suggest that the dosing regimen (i.e., 4 monthly vs. annually) rather than the total dose might determine the outcome," the authors write.

"This line of reasoning is supported by the temporal risk pattern that we observed and the fact that harm has not been reported in the numerous studies that have used more frequent dosing. Thus, it is reasonable to speculate that high serum levels of vitamin D or metabolites resulting from the large annual dose, subsequent decrease in the levels, or both might be causal. Furthermore, because the levels of 25-hydroxycholecalciferol demonstrated in this study could occur with other recommended dosing regimens, the outcome of this study suggests that safety of high-dose [vitamin D](#) supplementation warrants further study."

More information: *JAMA*. 2010;303[18]:1815-1822.

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