

RESEARCH SUMMARY

Supplemental Vitamin D and Incident Fractures in Midlife and Older Adults

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CLINICAL PROBLEM

Bone fractures are a public health burden that is predicted to increase with the aging of the U.S. population. Large randomized, controlled trials in the United States have been needed to examine whether daily vitamin D supplementation alone, without coadministered calcium, is effective for primary prevention of fractures.

CLINICAL TRIAL

Design: An ancillary study of a two-by-two factorial, randomized, controlled trial examined the effect of supplemental vitamin D₃ as compared with placebo on incident fractures in generally healthy midlife and older U.S. adults.

Intervention: 25,871 U.S. men 50 years of age or older and women 55 years of age or older, not selected for vitamin D deficiency, low bone mass, or osteoporosis, were randomly assigned to receive vitamin D₃ (2000 IU/day) or placebo and followed for a median duration of approximately 5 years. The primary end points were incident total, nonvertebral, and hip fractures.

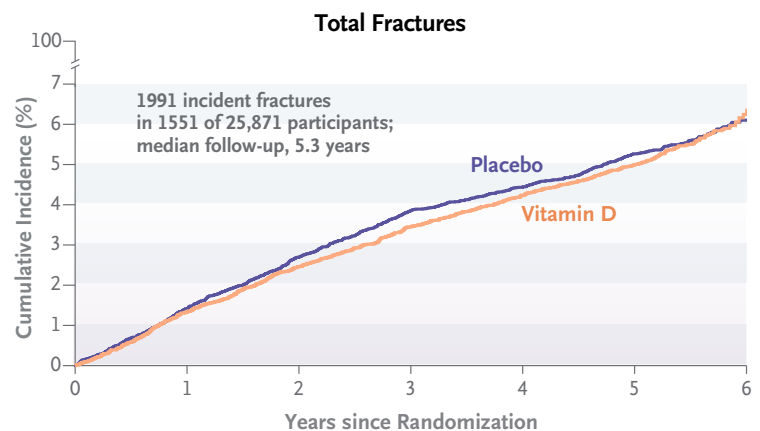
RESULTS

Efficacy: Supplemental vitamin D₃ had no significant effect on any primary end point in comparison with placebo. No effect modification was observed according to baseline demographic variables, body-mass index, nontrial use of supplemental calcium or vitamin D, or level of serum 25-hydroxyvitamin D.

Safety: The incidence of hypercalcemia and kidney stones did not differ substantially between the vitamin D and placebo groups.

LIMITATIONS

- Only one dose of vitamin D was used in this study.
- The analysis was not designed to test the effects of vitamin D in people with vitamin D deficiency.
- Findings may not be generalizable to adults with osteoporosis or older adults in institutions such as nursing homes.

**Confirmed Incident Fractures**

End Point	Vitamin D Group	Placebo Group	Hazard Ratio (95% CI)
Total fractures	769	782	0.98 (0.89–1.08)
Nonvertebral fractures	721	744	0.97 (0.87–1.07)
Hip fractures	57	56	1.01 (0.70–1.47)

CONCLUSIONS

Supplemental vitamin D₃ did not reduce the risk of bone fractures among midlife and older adults in the United States.

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