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## Research

# Patient level pooled analysis of 68 500 patients from seven major vitamin D fracture trials in US and Europe

The DIPART (vitamin D Individual Patient Analysis of Randomized Trials) Group

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**Objectives** To identify participants' characteristics that influence the anti-fracture efficacy of vitamin D or vitamin D plus calcium with respect to any fracture, hip fracture, and clinical vertebral fracture and to assess the influence of dosing regimens and co-administration of calcium.

**Design** Individual patient data analysis using pooled data from randomised trials.

**Data sources** Seven major randomised trials of vitamin D with calcium or vitamin D alone, yielding a total of 68 517 participants (mean age 69.9 years, range 47-107 years, 14.7% men).

**Study selection** Studies included were randomised studies with at least one intervention arm in which vitamin D was given, fracture as an outcome, and at least 1000 participants.

**Data synthesis** Logistic regression analysis was used to identify significant interaction terms, followed by Cox's proportional hazards models incorporating age, sex, fracture history, and hormone therapy and bisphosphonate use.

**Results** Trials using vitamin D with calcium showed a reduced overall risk of fracture (hazard ratio 0.92, 95% confidence interval 0.86 to 0.99,  $P=0.025$ ) and hip fracture (all studies: 0.84, 0.70 to 1.01,  $P=0.07$ ; studies using 10  $\mu\text{g}$  of vitamin D given with calcium: 0.74, 0.60 to 0.91,  $P=0.005$ ). For vitamin D alone in daily doses of 10  $\mu\text{g}$  or 20  $\mu\text{g}$ , no significant effects were found. No interaction was found between fracture history and treatment response, nor any interaction with age, sex, or hormone replacement therapy.

**Conclusion** This individual patient data analysis indicates that vitamin D given alone in doses of 10-20  $\mu\text{g}$  is not effective in preventing fractures. By contrast, calcium and vitamin D given together reduce hip fractures and total fractures, and probably vertebral fractures, irrespective of age, sex, or previous fractures.

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