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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 μg 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 μg or 20 μg , 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 μg 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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