High-dose oral vitamin D supplementation and mortality in people aged 65–84 years: the VIDAL cluster feasibility RCT of open versus double-blind individual randomisation

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Plain English summary

The VIDAL cluster feasibility RCT

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Plain English summary

High-dose vitamin D may reduce the risk of many diseases, but without large randomised controlled trials the evidence will remain inconclusive. We therefore proposed the Vitamin D and Longevity (VIDAL) trial, with 20,000 older people randomised to either no vitamin D medication or vitamin D medication for 5 years. The VIDAL feasibility study was conducted to establish the procedures required for the main trial, including assessment of recruitment, compliance (taking study treatment as directed) and contamination (how many control participants started taking vitamin D). This was done in two sets of general practitioner (GP) practices: (1) 'open' practices, in which participants knew their treatment allocation (2 years of 100,000 IU vitamin D monthly or no treatment), and (2) 'double-blind' practices, in which participants and their GPs did not know whether they were taking vitamin D or placebo oil.

We invited 11,376 men and women aged 65–84 years from 20 GP practices in England and 1615 (14%) took part. Ninety per cent of participants allocated to monthly oil took it for 2 years and few participants used vitamin supplements outside the trial, with no marked differences between open-label and double-blind arms. The best way to conduct the main trial will therefore depend on other considerations. A double-blind trial provides reliable evidence on effects where reporting could be influenced by you or your doctor knowing your treatment, which is important for many illnesses and any side effects of treatment. However, any long-term effects are likely to be considerably greater if treatment continues instead of stopping after 5 years when the main trial ends. An open trial is easier to conduct and, when it ends, those taking vitamin D can be offered a continuing supply so that the effect of lifelong treatment can be studied for major diseases and life expectancy, which are unlikely to be affected by individuals knowing whether or not they are taking vitamin D.

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This report

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