

## A deeper look at the RECORD Trial

Posted on [January 2, 2012](#) by James Larsen

Another randomized controlled trial study using vitamin D was just recently published, this one led by Alison Avenell in the UK, whose paper was published in the Journal of Endocrinology and Metabolism.

[Avenell et al. Long-Term Follow-Up for Mortality and Cancer in a Randomized Placebo-Controlled Trial of Vitamin D3 and/or Calcium \(RECORD Trial\). The Journal of Clinical Endocrinology & Metabolism November 23, 2011 jc.2011-1309](#)

The findings would disappoint any vitamin D enthusiast at first look. This was a 1999 study that looked at health outcomes in 5,000-plus community-dwelling elderly (median 77 years old) over time (median 6 years) using vitamin D and calcium. There were four groups: 800 IU D3, 1,000 mg calcium (as calcium carbonate), a group taking both and a group taking placebos.

What they found was that all-cause mortality, vascular disease mortality, cancer mortality, and cancer incidence did not differ significantly between any of the groups. Or in other words, vitamin D3 at 800 IU, calcium at 1,000 mg, or both, did not significantly improve health outcomes.

How can this be? Figuring out research and what it means can be organized into sort of a checklist. The big chunks for randomized controlled trials are:

1. Population. What does the population look like? Is it a representative population or is it somehow different?
2. The intervention(s). How much did they vary an intervention compared to a control group (no intervention)? How did they measure the intervention(s) and the outcome(s)?
3. Findings. Do the conclusions match the facts?

With this in mind, let's start by looking at the population in the study. 5,292 people joined the trial

between February 1999 and March 2002. The median length of follow-up was 6.2 years. The experiment was conducted on people over 70 years old, with the median age being 77. Eighty-five percent were female. Ninety-nine percent were white. They all had a previous history of low-trauma bone fractures and were being treated in 21 fracture clinics or orthopedic wards; however, anyone being treated for bone problems or taking supplements was excluded from the study. Most were probably D deficient or inadequate in vitamin D. Vitamin D status in a 60-person subgroup was 38 nmol/liter (15.2 ng/ml).

What we can conclude is that this was a skewed sample of elderly, white, and mostly female participants who had already had a broken bone and with no recent supplement/treatment history. Basically, they were not a healthy group (although they may be average or normal). Whenever somebody breaks a bone (aside from a car wreck, etc.), you really should see that break as a symptom and want to find out why their bones broke and fix those issues. Almost a third of them died during the study, mostly of cardiovascular disease and cancer.

Look at the interventions. 800 IU of D3. Was this an adequate, effective dose? The available limited data from a 60 person subgroup suggests most were D deficient (15.2 ng/ml) at entry. Supplementation of 800 IU/day increased levels to a 62 nmol/liter (24.8 ng/ml) in that 60 person subgroup. Therefore, everybody was still either deficient or inadequate by the most conservative criteria after taking 800 IU D3, although we cannot conclusively know the blood levels of the larger group.

The calcium and calcium-vitamin D groups received 1,000 mg of calcium as calcium carbonate a day. No testing was done on calcium levels or other minerals (see <http://www.betterbones.com/bonehealth/essentialnutrients.aspx> as to why this is important). The authors note that voluntary calcium supplementation is rare in the UK. Calcium carbonate is inexpensive, but has poor bio-availability, and typically come with, politely stated, “gastrointestinal symptoms.” Lappe reported a high drop-out rate in her D-calcium carbonate study in Navy entry training due to constipation.

Compliance was a huge problem.

*“Among those returning questionnaires (or after assuming nonresponders were noncompliers), the rates of pill takers were 67% (54%) at 12 months and 63% (45%) at 24 months. The worst-case scenario or compliance, assuming that people failing to return questionnaires did not take any tablets, indicated tablet taking on more than 80% of days for 45% at 2 yr, 35% at 3 yr, and 25% at 4 yr.”*

My best guess is that it's very, very hard to raise either D or calcium levels when folks don't actually take the pills.

Based on the study population and interventions, the conclusions should have been stated: “Low

dose D3 (800 IU) and calcium carbonate (1,000 mg elemental calcium) with unknown pre-post serum levels had no effect on a probably D deficient elderly (77 y/o median age), poorly compliant unsupervised community-dwelling population with a recent low-trauma fracture and no recent supplement/treatment history in all-cause mortality, vascular disease mortality, cancer mortality, and cancer incidence.” The data does not support the conclusion that vitamin D has no effect; they didn’t test all D doses or serum levels.

Further, I’d argue these outcomes are unrealistic even if the intervention was effective on serum levels. This is a group with “one foot in the grave and the other on a banana peel,” where single nutrients are being evaluated against death and long-latency diseases (heart disease and cancer). For example, is three years of D going to stop a 77 year-old smoker (12% were smokers) who smoked since she was 12 years old from dying? D is good, but not sure anything can be that good.



### About James Larsen

Jim spent 40 years working in or for the military trying to increase human performance and decrease injury and disease. It's a long uphill slog.

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## 2 Responses to *A deeper look at the RECORD Trial*

**roger.rolfe@sympatico.ca** said on January 2, 2012 at 2:14 pm

Great review, Jim. I’m glad to see you’re now blogging for the VDC. Congratulations. I look forward to further posts.



**James Larsen** said on January 5, 2012 at 4:04 pm



I'm not sure if I'm smart enough.

I'm still trying to figure out how NOT taking the pills results in a treatment effect.

I didn't take aspirin today and it didn't relieve my pain. My conclusion is aspirin is apparently ineffective. 😊

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