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# The D2-D3 Study: a randomised, double-blind, placebo-controlled food-fortification trial in women, comparing the efficacy of 15ug/d vitamin D2 vs vitamin D3 in raising serum 25OHD levels

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Poor vitamin D status (hypovitaminosis D) is a common problem in the UK; evidence shows prevalence is highest during the winter months, when serum 25OHD concentrations <25 and <40 nmol/l were found in 15·5% and 46·6% of the 1958 British birth cohort[(1)], compared to 3·2% and 15·4% respectively during the summer. As there are limited natural sources of vitamin D (diet & UVB rays) during the winter-time, supplementation and/or fortification of foods may be beneficial to proportions of the UK population. However, clarity on optimum type (vitamin D2 or D3) and dose of vitamin D required to maintain vitamin D status during the winter-time is urgently required[(2)].

The D2-D3 study aimed to examine and compare the efficacy of vitamin D2 vs. vitamin D3 in raising serum 25OHD (s25OHD) levels, and to assess whether 15ug/d is sufficient to raise or maintain s25OHD levels above `deficiency' or 'insufficiency' cut-offs (25 nmol/l and 40 nmol/l respectively) during the wintertime. In addition, the study aimed to compare the effect of two food vehicles on vitamin D bioavailability; orange juice and a biscuit.

A total of 335 healthy women aged 20–64yrs were recruited and randomised to receive either placebo (PL), vitamin D2 in orange juice (D2J), vitamin D2 in a biscuit (D2B), vitamin D3 in orange juice (D3J), or vitamin D3 in a biscuit (D3B) daily for 12-weeks during the wintertime.

At baseline, there were no significant differences in s25OHD levels between the five intervention groups. As shown in Table 1, after the 12-week intervention, all four vitamin D treatment groups showed a significant increase in s25OHD, whereas the placebo group had a significant decrease in s25OHD, as would be expected during the winter months. Food vehicle had no effect on the bioavailability of either vitamin D2 or vitamin D3.

**Table 1.** Baseline, week 12 and % change in 25OHD levels per treatment group

| Treatment Group | N | Baseline s25OHD (nmol/l) | | Week 12 s25OHD (nmol/l) | | % Change from Baseline | |
|---|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | Mean | SD |
| Placebo | 65 | 51·5 | 27·0 | 38·1[a] | 19·3 | −21·3 | 21·8 |
| D2J | 67 | 52·0 | 29·9 | 67·0[a] | 20·6 | 53·0 | 77·4 |
| D2B | 66 | 53·7 | 32·4 | 69·7[a] | 23·1 | 57·8 | 76·7 |
| D3J | 70 | 49·2 | 26·4 | 83·9[a] | 23·3 | 106·2 | 150·5 |
| D3B | 67 | 51·2 | 31·1 | 86·0[a] | 28·0 | 103·1 | 121·2 |

[a] $p < 0{\cdot}05$ compared to baseline

When comparing between the D2 and D3 intervention groups, irrespective of the food vehicle, the D3 group demonstrated a significantly greater increase in s25OHD over the 12-week intervention period ($p < 0{\cdot}0001$).

The present study provides conclusive evidence that food vehicle does not effect the bioavailability of vitamin D2 or vitamin D3, and that whilst both 15ug/d of vitamin D2 or D3 for 12-weeks are able to raise s25OHD levels during the wintertime, vitamin D3 is significantly more effective, facilitating a greater increase in s25OHD levels.

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1. Hyponnen & Power (2007) *Am J Clin Nutr* **85**, 860–8.
2. Tripkovic *et al.* (2012) *Am J Clin Nutr* **96**(6), 1357–64.