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The D2-D3 Study: comparing the efficacy of 15µg/d vitamin D2 vs. D3 in raising vitamin D status in both South Asian and Caucasian women, and the ethical implications of placebo treatment

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In the UK, the main source of vitamin D is sunlight as there are few dietary sources. Factors such as darker skin tone and a reduced exposure to sunlight due to clothing worn for cultural reasons, reduce the ability for individuals to make vitamin D from the action of UVB rays on skin. Therefore ethnic groups such as South Asian (SA) women are at a greater risk of deficiency year round, compared to white Caucasian (Cauc) women who may only be at risk during the winter months[(1)]. Supplementation with vitamin D may therefore have a beneficial role in such 'at-risk' population groups.

The D2-D3 study aimed to examine and compare the efficacy of 15µg/d vitamin D2 vs. vitamin D3 in raising serum 25OHD (s25OHD) levels, and to assess response within and between SA and Cauc women[(2)]. Participants were randomised to receive either placebo, 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. A total of *n*267 healthy women aged 20–64yrs successfully completed the D2-D3 study; *n*63 SA and *n*204 Cauc.

As shown in Table 1, baseline serum 25OHD (s25OHD) concentration of the Cauc groups were more than twice those of the SA groups. In response to vitamin D2 and D3 interventions, s25OHD significantly increased in both SA and Cauc groups ($p < 0{\cdot}001$), but percentage increase was higher in SA due to their poor s25OHD status at baseline. Placebo treatment led to a decrease in s25OHD in both the Cauc ($p < 0{\cdot}001$) and SA group (p 0·081).

Table 1. Baseline and week 12 s25OHD levels (nmol/l) in both SA and Cauc women

	South Asian					Caucasian				
		Baseline s25OHD		Week 12 s25OHD			Baseline s25OHD		Week 12 s25OHD	
Treatment Group	*n*	Mean	SD	Mean	SD	*n*	Mean	SD	Mean	SD
Placebo	*14*	24·7	13·0	19·5	7·7	*45*	59·2	23·2	43·9	18·2
D2J	*14*	34·7	22·7	52·9	13·2	*42*	57·7	26·2	73·9	18·7
D2B	*13*	29·7	23·0	49·4	17·0	*45*	58·4	24·7	73·6	18·0
D3J	*11*	33·2	24·4	65·4	14·7	*40*	51·9	19·5	87·9	23·0
D3B	*11*	21·5	15·0	56·4	18·5	*32*	55·7	26·2	95·6	27·5

At baseline, 61·1% of the SA participants were vitamin D 'deficient', with s25OHD <25 nmol/l, and at the end of the 12-week intervention period 85·7% of the SA participants within the placebo group were vitamin D 'deficient'.

This study provides evidence to show that s25OHD increases in response to either vitamin D2 or D3 in both SA and Cauc women, but that there is a greater response to vitamin D3 within both ethnic groups suggesting this may be the optimum form to use when treating deficiency. Furthermore this study data raises one key issue; whether it remains ethical to run randomised controlled vitamin D trials in SA populations, when there is a risk of receiving placebo treatment leading to greater levels of deficiency?

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1. Darling *et al.* (2013) *Osteoporos Int* **24**(2), 477–88.
2. Tripkovic *et al.* (2014) *Proc Nutr Soc* Submitted 2014.