A randomized trial of high-dose vitamin D2 in relapsing-remitting multiple sclerosis.


Source

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Abstract

OBJECTIVE:

Higher latitude, lower ultraviolet exposure, and lower serum 25-hydroxyvitamin D (25OHD) correlate with higher multiple sclerosis (MS) prevalence, relapse rate, and mortality. We therefore evaluated the effects of high-dose vitamin D2 (D2) in MS.

METHODS:

Adults with clinically active relapsing-remitting MS (RRMS) were randomized to 6 months' double-blind placebo-controlled high-dose vitamin D2, 6,000 IU capsules, dose adjusted empirically aiming for a serum 25OHD 130-175 nM. All received daily low-dose (1,000 IU) D2 to prevent deficiency. Brain MRIs were performed at baseline, 4, 5, and 6 months. Primary endpoints were the cumulative number of new gadolinium-enhancing lesions and change in the total volume of T2 lesions. Secondary endpoints were Expanded Disability Status Scale (EDSS) score and relapses.

RESULTS:

Twenty-three people were randomized, of whom 19 were on established interferon or glatiramer acetate (Copaxone) treatment. Median 25OHD rose from 54 to 69 nM (low-dose D2) vs 59 to 120 nM (high-dose D2) (p = 0.002). No significant treatment differences were detected in the primary MRI endpoints. Exit EDSS, after adjustment for entry EDSS, was higher following high-dose D2 than following low-dose D2 (p = 0.05). There were 4 relapses with high-dose D2 vs none with low-dose D2 (p = 0.04).

CONCLUSION:
We did not find a therapeutic advantage in RRMS for high-dose D2 over low-dose D2 supplementation.

CLASSIFICATION OF EVIDENCE:

This study provides Class I evidence that high-dose vitamin D2 (targeting 25OHD 130-175 nM), compared to low-dose supplementation (1,000 IU/d), was not effective in reducing MRI lesions in patients with RRMS.

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