

EFFICACY OF VITAMIN D SUPPLEMENTATION IN MULTIPLE SCLEROSIS: A PHASE II DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL

A.E. Oregani¹, M. Farrokhi^{1,3}, M. Etemadifar^{2,3}, A. Amani Beni^{1,3}, A. Rezaei⁴, L.M. Rivard⁴, Z. Tavassoli¹

¹*Department of Neurology, Faculty of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran*

²*Department of Neurology, Alzahra Hospital, Isfahan University of Medical Sciences, Isfahan, Iran*

³*Department of Neurology, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran; Multiple Sclerosis and Neuroimmunology Research Center, Isfahan, Iran*

⁴*Department of Molecular Biology, Cell Biology, and Biochemistry, Brown University, Providence, Rhode Island USA; Department of Neuroscience, Brown University, Providence, Rhode Island, USA*

amir.esteki7192@gmail.com

OBJECTIVES: Vitamin D metabolites are involved in immunological signaling that leads to suppression and regulation of autoimmune and inflammatory pathways. Therefore, vitamin D supplementation may be a viable method for treating autoimmune or inflammatory disease. This phase II double-blind randomized clinical trial seeks to investigate how treating with interferon beta-1 with vitamin D differs from treating with interferon beta-1 alone in MS patients.

METHODS: This randomized control trial used 59 MS patients split into two groups, one supplemented with vitamin D, to study the clinical effects that result after 6, 12, and 24 months. This study uses MRI analysis, evidence of clinical relapses, and EDSS (expanded disability scale) scores at baseline, 12 months and 24 months to perform statistical analysis. Type of statistical analysis varied with the outcomes being measured.

RESULTS: Patients treated with vitamin D experienced a decreased EDSS score ($P=.014$), a decreased rate of relapse ($P=.24$), and a decreased average number of GE lesions ($P.001$) after 2 years of vitamin D treatment.

CONCLUSION: Vitamin D is a viable way to supplement MS treatment and its role in autoimmune disease needs to be further investigated clinically. Our results suggest that in a population of MS patients, vitamin D levels are a good predictor of MS severity. In conclusion, vitamin D may not be a significant factor to consider in the etiology of MS, but rather a possible environmental exacerbating factor in the disease's progression.