

The Effects of Vitamin D3 Supplementation Alone and in a Combination with Omega-3 on the Association of C-Peptide with Glycemic Control; a Randomized Controlled Trial in People with Vitamin D Deficiency.

By

Omar Abdulmajeed Khadhim Al-tameemi

ID: 201815012

Supervisor

Prof. Mahmoud S Abu Samak

Abstract

This randomized controlled clinical trial (RCT) was designed to assess and compare the combined effect of vitamin D3 (VD3) and omega-3 fatty acid (n-3FAs) supplementations (D+) with the independent effect of two supplements on plasma HbA1c (A1c) and serum C-peptide (CP) levels in one hundred and fifteen healthy Jordanian participants with vitamin D deficiency (VDD).

Methodology One hundred thirty-six (136) participants enrolled in the study, 115 participants with VDD aged (30-64) years were recruited, and compliant with the study procedure were divided into four groups: (1) Control (n=21), (2) VD (n=30) treated with (50.000 IU/week) Cholecalciferol, (3) n-3FAs (n=30) received (1000) mg/daily of n-3FAs and, (4) D+ (n=34) treated with a combination of vitamin D (50.000 IU/week) and 1000 mg/daily of n-3FAs. Fasting serum levels of 25(OH)D, CP, and plasma A1c were assessed at baseline and at the eight weeks of follow up. The data were analyzed using SPSS.

Results Supplementation of VD3 alone resulted in increased serum 25(OH)D (15.42±5.70 to 38.00±12.33 ng/mL, $P<0.001$), plasma A1c (5.34 ± 0.30 to 5.52 ± 0.26 %, $P=0.007$), and serum CP (4.58±2.73 to 6.29±4.77 ng/mL, $P= 0.023$) levels. The n-3FAs intake led to significant decrease in serum 25(OH)D levels (22.31±6.20 to 14.91±5.72 ng/mL, $P<0.001$), significantly increase in A1c (5.32±0.40 to 5.60±0.46 %, $P< 0.001$) levels and insignificant increase in CP levels (7.43±4.47 to 7.90±4.34 ng/mL, $P=0.471$). Combination therapy resulted in increased serum 25(OH)D (13.89±4.66 to 37.94±11.35 ng/mL, $P=<0.001$), plasma A1c (5.36±0.30 to 5.73±0.30 %, $P=< 0.001$) and serum CP (5.34±2.80 to 6.94±3.64 ng/mL, $P= 0.039$) levels.

Conclusion After eight weeks of supplementation of VD3, n-3FA, or the combination on healthy participants with VDD, 25(OH)D increases in the VD3 and D+ groups and accompanied by CP and A1c levels elevation in VD and D+ groups. Besides, positive, medium strength and significant association were found between CP and A1c at the deficiency and insufficiency level of VD3. These results provide a vital insight into the effects of the VD3 or the combination of the patients with diabetics or people susceptible to developing T2DM, suffering from VDD.

Trial registration: This trial was registered at clinicaltrials.gov as NCT04307784 (Appendix 8).

Keywords: *vitamin D3, omega-3 fatty acids, serum levels of C-peptide, plasma HbA1c, vitamin D deficiency.*