

The effect of Weekly supplements on the serum 3 50,000 IU vitamin D levels of selected cytokines involved in cytokine storm of Covid-19; A randomized clinical trial in the Covid-19 uninfected Jordanian people with vitamin D deficiency

**Prepared by: Dana Bader
Supervisor: Prof. Mahmoud Abu Samak**

Abstract

Aim

Vitamin D deficiency is widespread in human populations and has been linked to immune dysfunction. This randomized clinical trial aims to assess the effects of a high dose of cholecalciferol (VD3) supplements (50,000 IU/week) on circulating cytokines associated with cytokine storm in vitamin D deficient [blood hydroxy vitamin D (25OHD) < 30 ng/mL] adults men and women aged 30–66 from Jordan .

Methodology

The trial included 50 participants receiving VD3 supplements (50,000 IU/week) for 8 weeks; the same number was assigned to the control group and did not receive vitamin D supplements. Interleukin-6 (IL-6), Interleukin-1 β (IL-1 β) Interleukin-10 (IL-10), and tumor necrotic factor- α (TNF- α) were measured in serum at baseline and at 10 weeks (wash out: 2 weeks). Changes in 25OHD and cytokines were assessed using paired parametric tests. xv

Results

VD3 supplementation increased serum 25OHD (16.41 ± 4.99 to 41.39 ± 12.19 ng/mL, $P < 0.001$), IL-6 (5.5 ± 6.51 to 26.99 ± 14.47 pg/mL, $P < 0.001$), IL-10 (2.01 ± 0.59 to 4.46 ± 4.67 pg/mL, $P = 0.001$), IL-1 β (3.22 ± 0.99 to 7.63 ± 2.36 pg/mL, $P < 0.001$) levels significantly. Compared with the baseline, the mean serum level of TNF- α in VD3 supplemented group showed insignificantly increased (33.34 ± 6.36 to 33.50 ± 6.18 pg/mL, $P = 0.899$).

Conclusion

High doses of VD3 significantly raised IL-6 level which is an important marker since an increase in its concentration is associated with an increase in the levels of cytokine storm. Although the observations of this trial may refer to a potential negative effects of VD3 supplementation during cytokine storm, further trials are needed to clarify potential benefits of VD3 supplementation during cytokine storm.

Trial registration: This trial was registered at clinicaltrials.gov as NCT04476745

Keywords: vitamin D deficiency, vitamin D3, cytokine, storm, Interleukin 6, Interleukin 10, Interleukin 1 β , TNF- α .