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Short term, high-dose vitamin D supplementation for COVID-19 disease: a randomised, placebo-controlled, study (SHADE study)

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Abstract

Background: Vitamin D has an immunomodulatory role but the effect of therapeutic vitamin D supplementation in SARS-CoV-2 infection is not known.

Aim: Effect of high dose, oral cholecalciferol supplementation on SARS-CoV-2 viral clearance.

Design: Randomised, placebo-controlled.

Participants: Asymptomatic or mildly symptomatic SARS-CoV-2 RNA positive vitamin D deficient (25(OH)D < 20 ng/ml) individuals.

Intervention: Participants were randomised to receive daily 60 000 IU of cholecalciferol (oral nano-liquid droplets) for 7 days with therapeutic target 25(OH)D > 50 ng/ml (intervention group) or placebo (control group). Patients requiring invasive ventilation or with significant comorbidities were excluded. 25(OH)D levels were assessed at day 7, and cholecalciferol supplementation was continued for those with 25(OH)D < 50 ng/ml in the intervention arm. SARS-CoV-2 RNA and inflammatory markers fibrinogen, D-dimer, procalcitonin and (CRP), ferritin were measured periodically.

Outcome measure: Proportion of patients with SARS-CoV-2 RNA negative before day-21 and change in inflammatory markers.

Results: Forty SARS-CoV-2 RNA positive individuals were randomised to intervention (n=16) or control (n=24) group. Baseline serum 25(OH)D was 8.6 (7.1 to 13.1) and 9.54 (8.1 to 12.5) ng/ml (p=0.730), in the intervention and control group, respectively. 10 out of 16 patients could achieve 25(OH)D > 50 ng/ml by day-7 and another two by day-14 [day-14 25(OH)D levels 51.7 (48.9 to 59.5) ng/ml and 15.2 (12.7 to 19.5) ng/ml (p<0.001) in intervention and control group, respectively]. 10 (62.5%) participants in the intervention group and 5 (20.8%) participants in the control arm (p<0.018)

became SARS-CoV-2 RNA negative. Fibrinogen levels significantly decreased with cholecalciferol supplementation (intergroup difference 0.70 ng/ml; $P=0.007$) unlike other inflammatory biomarkers.

Conclusion: Greater proportion of vitamin D-deficient individuals with SARS-CoV-2 infection turned SARS-CoV-2 RNA negative with a significant decrease in fibrinogen on high-dose cholecalciferol supplementation.

Trial register number: [NCT04459247](#).

Keywords: Diabetes & endocrinology; Infectious diseases; Virology.

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