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Title: Substitution of vitamin D in patients with moderate to severe persistent asthma: A randomized, placebo-controlled pilot study

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Body: Background: Vitamin D_3 stimulates glucocorticoid-induced IL-10 synthesis by regulatory T cells in patients with asthma. IL-10 is a potent antiinflammatory cytokine that can block asthmatic inflammation. Objective: To study whether short-term calcitriol affects lung function and symptoms in patients with moderate to severe persistent asthma treated with a combination of long-acting beta-2-agonists and inhaled corticosteroids. Methods: 20 outpatients (8m, 12f) with moderate to severe persistent asthma (mean age 58.4y, 36-83) were enrolled in this randomized, placebo-controlled, double-blind, double-dummy pilot trial with random crossover design. All were treated with a stable dose equivalent to ≥400 ug/day of budesonide and ≥12 ug/day of formoterol for at least 4 weeks. Patients were randomized to receive either calcitriol 1.0 µg once daily or placebo. Each treatment phase lasted for 4 weeks, interrupted by a 3-week treatment washout period. Treatment effect was calculated by subtracting baseline values from end of treatment values and using a linear mixed effects model to correct for period and sequence effect. Results: Baseline FEV1 was 69.2 %pred. (±11.9), 25-hydroxyvitamin D level 46.6 nmol/L (±21.8). FEV1 %pred. increased by 1.4 % (±7.5) during calcitriol compared to 0.2 % (±5.5) during placebo treatment (p=0.64, n.s.). FE_{NO}, bronchial hyperreactivity, peak flow, asthma symptom scores and use of short-acting beta-2-agonists were also not significantly different between calcitriol and placebo periods. Conclusion: Calcitriol did not improve lung function and asthma symptoms in this short term pilot study (ClinicalTrials.gov number, NCT 00712205).