

Papas KA, Sontag MK, Pardee C, Sokol RJ, Sagel SD, Accurso FJ, and Wagener JS. **A pilot study on the safety and efficacy of a novel antioxidant rich formulation in patients with cystic fibrosis.** Journal of Cystic Fibrosis 2008 7:60-67.

**Background:** Pancreatic insufficiency and a diminished bile acid pool cause malabsorption of important essential nutrients and other dietary components in cystic fibrosis (CF). Of particular significance is the malabsorption of fat-soluble antioxidants such as carotenoids, tocopherols and coenzyme Q10 (CoQ10). Despite supplementation, CF patients are often deficient in these compounds, resulting in increased oxidative stress, which may contribute to adverse health effects.

**Objective:** This pilot study was designed to evaluate the safety of a novel micellar formulation (CF-1) of lipophilic nutrients and antioxidants and to determine its efficacy in improving plasma levels of these compounds and reducing inflammatory markers in induced sputum.

**Design:** Ten CF patients, ages 8 to 45 years old, were given orally 10 ml of the CF-1 formulation daily for 56 days after a 21-day washout period in which subjects stopped supplemental vitamin use except for a standard multivitamin. Plasma obtained at -3, 0 (baseline), 1, 2, 4, and 8 weeks was assayed for  $\beta$ -carotene,  $\alpha$ - and  $\gamma$ -tocopherol, retinol, and CoQ10 as well as for safety parameters (comprehensive metabolic panel and complete blood count). In addition, pulmonary function was measured and induced sputum was collected for markers of inflammation and quantitative bacterial counts both pre and post dosing.

**Results:** CF-1 was deemed safe as there were no serious adverse effects attributable to CF-1, no abnormalities in laboratory parameters and the levels of the measured nutrients did not exceed the normal range. Supplementation with CF-1 significantly increased  $\beta$ -carotene levels at all post-dosing time points when compared to screening and baseline. In addition,  $\gamma$ -tocopherol and CoQ10 significantly increased from baseline in all patients. Induced sputum myeloperoxidase significantly decreased and there was a trend toward decreases in PMN elastase and total cell counts with CF-1. There was a significant inverse correlation between the antioxidant score and induced sputum changes in IL-8 and total neutrophils. Lung function and sputum bacterial counts were unchanged.

**Conclusion:** The novel CF-1 formulation safely and effectively increased plasma levels of important fat-soluble nutrients and antioxidants. In addition, improvements in antioxidant plasma levels were associated with reductions in airway inflammation.