primary studies - published RCT

Fat-Soluble Vitamins in Standard vs. Liposomal Form Enriched with Vitamin K2 in Cystic Fibrosis: A Randomized Multi-Center Trial.

Code: PM35054157 **Year:** 2022 **Date:** **Author:** Nowak JK

Study design (if review, criteria of inclusion for studies)

Multi-center randomized controlled trial

Participants

100 pancreatic-insufficient patients with CF.

Interventions

A liposomal fat-soluble vitamin formulation containing vitamin K2. The liposomal formulation contained vitamin A as retinyl palmitate (2667 IU daily) and beta-carotene (1333 IU), D3 (4000 IU), E (150 IU), K1 (2 mg), and K2 as menaquinone-7 (400 µg). It was compared with the standard vitamin preparations in the closest possible doses (2500 IU, 1428 IU, 4000 IU, 150 IU, 2.14 mg, respectively; no vitamin K2) over 3 months.

Outcome measures

The main outcome was the change of vitamin status in the serum during the study (liposomal vs. standard). The secondary outcome was the vitamin status at the trial end.

Main results

Forty-two patients finished the trial in the liposomal and 49 in the control group (overall 91 pts: 22.6 Â± 7.6 years, 62.6% female, BMI 19.9 Â± 2.8 kg/m(2), FEV1% 70% Â± 30%). The main outcome was the change of vitamin status in the serum during the study (liposomal vs. standard): all-trans-retinol (+1.48 Â± 95.9 vs. -43.1 Â± 121.4 ng/mL, p = 0.054), 25-hydroxyvitamin D3 (+9.7 Â± 13.4 vs. +2.0 Â± 9.8 ng/mL, p = 0.004), Î±-tocopherol (+1.5 Â± 2.5 vs. -0.2 Â± 1.6 Âµg/mL, p

Authors' conclusions

The liposomal fat-soluble vitamin supplement containing vitamin K2 was superior to the standard form in delivering vitamin D3 and E in pancreatic-insufficient patients with CF. The supplement was also more effective in strengthening vitamin K-dependent carboxylation, and could improve vitamin A status.

http://dx.doi.org/10.3390/jcm11020462

See also

J Clin Med. 2022 Jan 17;11(2):462. doi: 10.3390/jcm11020462.

Keywords

Vitamin A; Vitamin D; Vitamin E; Vitamin K; Vitamins; pharmacological_intervention; Supplementation; Antioxidants; Gastrointestinal Diseases; Pancreas insufficiency; Pancreatic Diseases;