primary studies - published RCT

Effect of vitamin K1 supplementation on vitamin K status in cystic fibrosis patients.

Code: PM9161943 **Year:** 1997 **Date:** 1997 **Author:** Beker LT

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

Randomised cross-over trial (2 periods of 4 weeks).

Participants

confirmed diagnosis of CF by duplicate sweat test clinically stable as determined by physical exam; afebrile Randomised: N = 18 (8 male, 10 female); mean age 20 years (Range 13 - 35 years). Inclusion criteria moderate lung disease based on an average radiograph score of 15 using the Brasfield scoring method within or above the fifth NCHS height percentile for age and body mass index (BMI) â‰¥20 AST/ALT levels within the normal range, and normal plasma albumin levels Exclusion criteria Withdrawal or loss to follow-up: None reported. without cholestasis or overt liver disease elevated AST/ALT. CF Clinic Children's National Medical Center (CNMC), Washington DC.

Interventions

4 weeks of first treatment then crossed over to the other treatment for a second 4-week period. Concomitant medications permitted: cephalosporin (13); sulfamethoxazole (3); erythromycin (1); bronchodilators; standard multivitamins and 200 - 400 IU vitamin E. Intervention: 5 mg oral vitamin K1 supplementation per week. Control: no supplementation.

Outcome measures

plasma vitamin K1 and vitamin K1-2,3 epoxide plasma PIVKA-II Primary outcomes: none reported Secondary outcomes (assessments at entry and end of each trial period) serum osteocalcin 3-day dietary intake records were completed during each treatment period, but these did not correspond with the nutritional parameters sought as secondary outcomes for this review. Patient compliance was verified by the trial coordinator at each visit.

Main results

The mean concentration of plasma vitamin K1 for the supplemented group was significantly higher than the unsupplemented group, [0.34 nmol/L and 0.21 nmol/L, respectively (p

Authors' conclusions

In contrast to other studies in cystic fibrosis, this study demonstrated a need for vitamin K1 supplementation. The carboxylation state of osteocalcin and PIVKA-II were the most sensitive indices of changes in vitamin K1 status. Although the 5 mg vitamin K1/week dose improved these vitamin K parameters, normal levels were not achieved.

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See also

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Keywords

1-Carboxyglutamic Acid; Adolescent; Adult; non pharmacological intervention - diet; Oral; pharmacological_intervention; Supplementation; vitamins; Vitamin K; Vitamins; Malabsorption; Nutrition Disorders; Erythromycin; Macrolides; Anti-Bacterial Agents; Antioxidants;