

primary studies - published RCT

## Levofloxacin inhalation solution (MP-376) in patients with cystic fibrosis with *Pseudomonas aeruginosa*.

Code: PM21471106

Year: 2011 Date: 2014

Author: Geller DE

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

RCT

### Participants

Children with cystic fibrosis (CF) and pancreatic insufficiency (PI)

### Interventions

Children were randomized to daily LXS or an isocaloric placebo comparison supplement for 12 months.

### Outcome measures

Serum vitamins A (retinol), D (25-hydroxyvitamin D[25D]), E (alpha-tocopherol, alpha-tocopherol:cholesterol ratio), and K (percentage of undercarboxylated osteocalcin [%ucOC] and plasma proteins induced by vitamin K absence factor II [PIVKA II]) were assessed at baseline and 12 months. Dietary intake was determined using 3-day weighed food records and supplemental vitamin intake by a comprehensive questionnaire. Results: A total of 58 subjects (32 boys, age 10.3+2.9 years [mean+standard deviation]) with complete serum vitamin, dietary and supplemental vitamin data were analyzed.

### Main results

A total of 58 subjects (32 boys, age 10.3+2.9 years [mean+standard deviation]) with complete serum vitamin, dietary and supplemental vitamin data were analyzed. After adjusting for dietary and supplemental vitamin intake, serum retinol increased 3.0+1.4 mug/dL (coefficient+standard error) (adjusted R<sup>2</sup>=0.02, P=0.03) and vitamin K status improved as demonstrated by a decreased percentage of undercarboxylated osteocalcin of -6.0%+1.6% by 12 months (adjusted R<sup>2</sup>=0.15, P

### Authors' conclusions

Vitamins A and K status improved, whereas vitamins D and E status was unchanged during 12 months of LXS and isocaloric placebo comparison supplement in children with CF and PI. Copyright 2014 by ESPGHAN and NASPGHAN. Unauthorized reproduction of this article is prohibited.

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### See also

Am J Respir Crit Care Med. 2011 Jun 1;183(11):1510-6. Epub 2011 Feb 25.

### Keywords

Child; Gastrointestinal Diseases; Lym-X-Sorb; non pharmacological intervention - diet; Pancreas insufficiency; Pancreatic Diseases; placebo; Malabsorption; Nutrition Disorders; Powders; Phosphatidylcholines; Gastrointestinal Agents; essential fatty acids; Vitamins; pharmacological\_intervention;