

primary studies - published RCT

## **Denufosal tetrasodium in patients with cystic fibrosis and normal to mildly impaired lung function.**

**Code:** PM21169471

**Year:** 2011 **Date:** 2015

**Author:** Accurso FJ

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

Randomized placebo-controlled double blind trial.

### **Participants**

Children with CF and PI

### **Interventions**

Children were randomized to LXS or placebo (12-month)

### **Outcome measures**

Dietary choline intake, plasma cholines, plasma and fecal phospholipids, coefficient of fat absorption (CFA), pulmonary function, growth status, body composition, and safety measures were assessed. Magnetic resonance spectroscopy for calf muscle choline and liver fat were assessed in a subgroup and compared to a healthy comparison group matched for age, sex and body size.

### **Main results**

110 subjects were enrolled (age 10.4 +/- 3.0 years). Baseline dietary choline, 88% recommended, increased 3-fold in the LXS group. Plasma choline, betaine, and dimethylglycine increased in the LXS but not placebo ( $P = 0.007$ ). Plasma lysophosphatidylcholine and phosphatidylcholine (PC) increased and fecal PC/phosphatidylethanolamine ratio decreased ( $P$

### **Authors' conclusions**

LXS had improved choline intake, plasma choline status and muscle choline stores, compared with placebo. The choline-rich supplement was safe, accepted by participants and improved choline status in children with CF.

<http://dx.doi.org/10.1164/rccm.201008-1267OC>

### **See also**

Am J Respir Crit Care Med. 2011 Mar 1;183(5):627-34. Epub 2010 Dec 17.

### **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;