primary studies - published RCT

Efficacy and tolerability of a new formulation of pancrelipase delayed-release capsules in children aged 7 to 11 years with exocrine pancreatic insufficiency and cystic fibrosis: a multicenter, randomized, double-blind, placebo-controlled, two-period crossover, superiority study.

Code: PM20171415 **Year:** 2010 **Date:** 2013 **Author:** Graff GR

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

Randomized controlled trial

Participants

Forty-one CF patients aged from 6 to 12 years

Interventions

High-dose DHA (100 mg/kg/day in the first month and 1g per day thereafter through a 12-month supplementation) or placebo (germ oil).

Outcome measures

Primary outcome was percentage change in plasma AA:DHA ratio. Secondary outcomes were changes in the number of pulmonary exacerbations compared to previous year, lung function, BMI, skinfold thicknesses, and body composition assessed by DXA and in serum concentrations of C-reactive protein, cytokines and vitamin (alpha-tocopherol and retinol).

Main results

Compared to the control group plasma AA:DHA ratio decreased in the intervention group after 6 months (median percentage changes: -73% in the intervention group vs. -10% in the control group, P=0.001). No differences were detected between groups for secondary outcomes. Despite a decrease of the AA/DHA ratio, DHA supplementation for one year did not induce any significant biochemical and clinical improvement in CF patients.

http://dx.doi.org/10.1016/j.clinthera.2010.01.012

See also

Clin Ther. 2010 Jan;32(1):89-103.

Keywords

Child; Anti-Bacterial Agents; Docosahexaenoic Acid -DHA-; non pharmacological intervention - diet; Supplementation; essential fatty acids; omega-3;