

primary studies - published RCT

Tiotropium Respimat(R) in cystic fibrosis: Phase 3 and Pooled phase 2/3 randomized trials.

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

Double-blind randomized active placebo-controlled trial

Participants

Children with cystic fibrosis (CF) and pancreatic insufficiency (PI). Subjects (n = 66, 10.5+/-3.0 yrs, 39% female) with baseline CFA who completed a three-month treatment with Encala or a calorie and macronutrient-matched placebo were included in this subgroup analysis. Subjects were categorized by median baseline CFA: low CFA (<88%) and high CFA (>=88%).

Interventions

A readily absorbable structured lipid (Encala, Envara Health, Wayne, PA)

Outcome measures

At baseline and 3-month evaluations, CFA (72-hour stool, weighed food record) and height (HAZ), weight (WAZ) and BMI (BMIZ) Z-scores were calculated. Fasting plasma fatty acid (FA) concentrations were also measured.

Main results

Subjects in the low CFA subgroup had significantly improved CFA (+7.5+/-7.2%, mean 86.3+/-6.7, p = 0.002), and reduced stool fat loss (-5.7+/-7.2 g/24 hours) following three months of EncalaTM treatment. These subjects also had increased plasma linoleic acid (+20%), alpha-linolenic acid (+56%), and total FA (+20%) (p

Authors' conclusions

Subjects with CF, PI and more severe fat malabsorption experienced greater improvements in CFA, FA and growth after three months of Encala treatment. Encala was safe, well-tolerated and efficacious in patients with CF and PI with residual fat malabsorption and improved dietary energy absorption, weight gain and FA status in this at-risk group.

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See also

J Cyst Fibros. 2015 Mar 25. pii: S1569-1993(15)00059-4. doi: 10.1016/j.jcf.2015.03.004.

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;