primary studies - published RCT

Efficacy and safety of ivacaftor in patients with cystic fibrosis who have an Arg117His-CFTR mutation: a double-blind, randomised controlled trial.

Code: PM26070913 **Year:** 2015 **Date:** 2020 **Author:** Moss RB

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

Randomized, double-blind, parallel, placebo-controlled trial.

Participants

96 CF patients (age >2 months) 44 female, age 14.6±11.9 years (48 DHA and 48 placebo) were included.

Interventions

Patients were randomized to receive a seaweed DHA oil solution (50 mg/Kg/day) or matching placebo for 48 weeks.

Outcome measures

Primary outcomes were pulmonary (interleukin [IL]-8), systemic (IL-8) and intestinal (calprotectin) inflammatory biomarkers. Secondary outcomes included other pulmonary (IL-1Î², IL-6, neutrophil elastase, lactate and calprotectin) and systemic (serum-IL-1Î², IL-6) inflammatory biomarkers, as well as clinical outcomes (FEV(1), pulmonary exacerbations, antibiotic use, nutritional status and quality of life).

Main results

At trial completion, there were no differences in all primary outcomes [serum-IL-8 (p=0.909), respiratory-IL-8 (p=0.384) or fecal calprotectin (p=0.948)], all secondary inflammatory biomarkers, or in any of the clinical outcomes evaluated. There were few adverse events, with similar incidence in both study groups.

Authors' conclusions

In this study, long-term DHA supplementation in CF patients was safe, but did not offer any benefit on inflammatory biomarkers, or in clinical outcomes compared with placebo. (NCT01783613).

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See also

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Keywords

Adult; Aged; Child; Docosahexaenoic Acid -DHA-; non pharmacological intervention - diet; Oral; placebo; Supplementation; essential fatty acids; omega-3;