Two randomized, double-blind, multicenter, placebo controlled trials.

Patients with quiescent CD with CDAI<150 were randomly assigned to receive either 4g/day of omega-3 fatty acids or placebo for up to 58 weeks. No other treatments for CD were permitted.

<u>Primary endpoint</u>: Clinical relapse defined as CDAI of 150 or greater and an increase of >70 points from baseline.

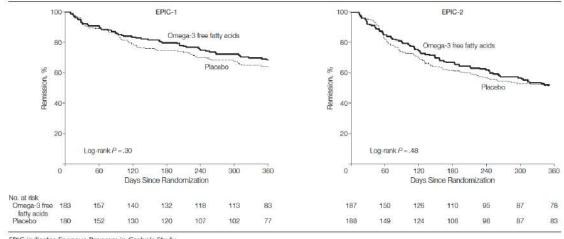
Results: EPIC 1 N=363; EPIC 2 N=375

- Rate of relapse at year 1 in EPIC 1 was 31.6% omega 3 vs 35.7% placebo, p=0.3
- Rates of relapse at year 1 in EPIC 2 were 47.8% omega 3 vs 48.8% placebo, p=0.48
- Serious adverse events were uncommon and were related to CD

Conclusion:

In these trials, treatment with omega-3 free fatty acids was not effective for the prevention of relapse in Crohn disease.

Figure 2. Kaplan-Meier Estimates of the Time to Relapse in the Omega-3 Free Fatty Acids and Placebo Groups for EPIC-1 and EPIC-2



EPIC indicates Epanova Program in Crohn's Study.

