

Docosahexaenoic Acid Does Not Improve Visual Function in Patients With Autosomal Recessive Stargardt Disease

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Abstract

Purpose: : A case report¹ proposed that docosahexaenoic acid (DHA) supplementation may be useful to improve visual function in patients with autosomal dominant Stargardt-like macular dystrophy due to mutations in the ELOVL4 gene (adSTGD). A clinical trial designed to test this hypothesis is underway. The purpose of this study was to determine if a similar beneficial DHA effect could be detected in patients with autosomal recessive Stargardt disease (arSTGD).

Methods: : This study was a randomized, placebo-controlled, double-masked clinical trial using a crossover design. Nine women (ages 26 to 63 years, mean age 39 years) participated in the trial. They were screened for mutations in the ABCA4 gene. After two baseline evaluations, they were randomized to either a DPDP or a PDPD sequence, where D indicates three months of DHA (1000 mg po bid), and P indicates three months of placebo. The primary outcome variable was multifocal ERG (mfERG) amplitude density. Secondary outcome variables were visual acuity (ETDRS letter score), visual field (HFA 10-2, sum of thresholds), color vision (D-15 panel, confusion index), and flicker ERG (32 Hz 1st harmonic amplitude).

Results: : Statistical analysis was carried out using a general linear model. The model adjusted for treatment, sequence and period, and took into account repeated measures on each patient. There were no significant differences in mfERG amplitude between DHA and placebo periods. The least squares means for DHA and placebo were 1.12 and 1.14 log nV/deg², respectively, and their difference was - 0.02 (95% confidence limits: - 0.05, 0.02) log nV/deg², $p = 0.38$. Similar modest, non-significant differences were obtained for visual acuity, visual field, color vision, and flicker ERG outcomes. As expected, we saw a marked (threefold) increase in serum DHA concentration with DHA supplementation ($p = 0.005$).

Conclusions: : We did not find evidence to support the premise that DHA improved visual function in this arSTGD cohort. This suggests that the results obtained in adSTGD are likely to be due to the treatment of a retinal DHA deficiency rather than to a nonspecific effect of DHA on cone function. We did not encounter any adverse events attributable to DHA. This study was not designed to assess if DHA slows the progression at arSTGD. The reproducibility of mfERG measurements in this study implies that the mfERG meets one of the essential requirements of an outcome measure in a clinical trial.¹ MacDonald, IM, et al., *Br J Ophthalmol*, 2004; 88: 305-306.

Clinical Trial: : www.clinicaltrials.gov NCT00060749

Keywords: retinal degenerations: hereditary • macula/fovea • electroretinography: clinical

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