



Effect of Oral Re-Esterified Omega-3 Nutritional Supplementation on Dry-Eye Disease: Double-Masked Randomized Placebo-Controlled Study

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Purpose

Oral nutrition is considered primary therapy for dry eye disease and meibomian gland dysfunction. The purpose of this study was to assess the effect of oral re-esterified omega-3 fatty acids on tear osmolarity, MMP-9, ocular surface disease Index (OSDI), tear break-up time (TBUT), Schirmer's score, corneal staining and omega Index.

Methods

This was a multicenter, prospective, interventional, placebo controlled, double masked, randomized trial. On Final analysis, 105 patients with dry eye disease were randomized to receive four capsules (2 gm) once a day containing 1680mg EPA and 560mg DHA (PRN Dry Eye Omega Benefits) for 3 months or four capsules of placebo. All patients underwent a screening, baseline, 6 week and 12 weeks visit. On each visit patients were tested for tear osmolarity, MMP-9, fluorescein corneal staining, Schirmer's testing, and OSDI. On the screening exam and week 12 evaluation patients had their omega index tested.

Results

Mean tear osmolarity at baseline, week 6 and week 12 was 326.0±15.4, 317.0±20.5 and 317.7±19.7 mOsm/L for the placebo group versus 326.2±15.8, 309.4±13.4, 306.9±12.1 mOsm/L for the omega-3 group (**P=0.042 Week6; 0.004 Week 12**) OSDI placebo group at baseline, week 6 and 12 was, 27.1± 22.9, 19.6 ±17.0, and 22.0±19.3 compared to 32.4±19.2, 21±14.4, and 15.5±11.0 for the omega group. (**P=0.285 Week6; 0.002 Week12**) Tear Break up Time placebo group at baseline, week 6 and 12 was 4.61±2.04, 5.55±2.43 and 5.81±3.13 compared to 4.78± 2.96, 6.64 ± 3.17 and 8.25±4.78 for the omega group. (**P=0.126 Week 6; 0.002 Week 12**) Omega Index levels statistically improved at 12 weeks in the omega group vs placebo (p<0.001).

Conclusion

This study demonstrated that oral consumption of re-esterified omega-3 fatty acids (1680 mg EPA and 560 mg DHA once daily for 12 weeks) is an effective treatment of dry eye disease and results in a statistically significant improvement in tear osmolarity, OSDI, tear break up time and omega index levels.