Diabetes Neuropathy Trial in Analysis

Auum was the product sponsor for a Canadian Diabetes Association funded clinical trial investigating if 12-months of seal oil supplementation could stop the progression of diabetic neuropathy in individuals with type 1 diabetes. Currently there are no known interventions to stop the progression of nerve damage in diabetes.

Data collection for this trial is complete and the research team is very excited to be working on the analysis of this potentially groundbreaking study. Results were presented at National and International Conferences in July and September 2016.

Omega-3 polyunsaturated fatty acids (N-3 PUFA) are essential for the development and maintenance of nerves, but have not yet been investigated for their ability to stop the progression of DSP.

As posted in the Canadian Journal of Diabetes, October 2016

Background: Diabetic sensorimotor peripheral neuropathy (DSP) is the leading complication in diabetes mellitus (DM) for which there are currently no intervention therapies. Corneal nerve fibre length (CNFL) measured by in vivo corneal confocal microscopy (IVCCM) is a biomarker for DSP onset and progression in T1DM (type 1 diabetes mellitus). Corneal nerve fibre length (CNFL) was measured in vivo is a biomarker for DSP onset and progression. Longitudinal data shows an annual CNFL change of -1.6% (shortening) in T1DM, while healthy controls change +5% (growth). Omega-3 polyunsaturated fatty acids (N-3 PUFA) are essential for the development and maintenance of nerves, but have not yet been investigated for their ability to stop the progression of Diabetic sensorimotor peripheral neuropathy (DSP) or Diabetic peripheral neuropathy (DPN).

Methods: Individuals with type 1 (T1DM) and evidence of DSP as determined by a Toronto Clinical Neuropathy Score (TCNS)≥1 were recruited to participate in an open-label trial of seal oil N-3 PUFA supplementation provided by Auum (10 mL.d-1; 750 mg EPA, 560 mg DPA and 1020 mg DHA) for 1 year (NCT02034266). The primary outcome was the 1-year change in CNFL, and secondary outcomes included gold-standard clinic tests.

Results: Forty participants (53% female), aged 48±14, BMI 28.1±5.8 with diabetes duration of 27±18 years were enrolled in the trial. At baseline, 27 participants had clinical DSP and 7 were at risk for future DSP. After 12 months, TCNS changed from 6 to 4 (p=0.1). This double blinded study result showed a Baseline CNFL was 8.3±2.9 mm/mm2 and increased 29% to 10.1±3.7 mm/mm2 (p=0.006).

Conclusion: These findings show that 12 months of seal oil supplementation can stop the progression of DSP measured by CNFL. N-3 supplementation could be a targeted nutritional therapy to address small nerve fibre damage in DSP.

Auum mammalian omega-3s are structurally different from fish oils allowing omega-3s to be absorbed under the tongue (sublingually). This allows Auum omega-3s to quickly enter the blood stream without passing through the digestive tract.

.../page 2

Auum mammalian omega-3s naturally contain DPA along with EPA and DHA. Just like EPA, DPA is an essential omega-3 that is important for resolving inflammation throughout the body and is not present in any appreciable amounts in fish oil.

Auum omega-3s are carefully processed using low-heat technology. All products are 3rd party tested and licensed with Health Canada Natural Product Numbers (NPN).

Research

Diabetes and Neuropathy

Neuropathy is the most common complication of Diabetes, affecting over 50% of individuals, causing pain, numbness and the loss of sensation. Currently there is no treatment to stop the onset or progression of neuropathy. Auum was the product sponsor for a Canadian Diabetes Association (now Diabetes Canada) funded clinical trial investigating if 12-months of Auum seal oil supplementation could stop the progression of diabetic neuropathy in individuals with Type 1 diabetes. Study results published in the Canadian Journal of Diabetes Oct 2016 state **Conclusion:** These findings show that 12 months of seal oil supplementation can stop the progression of DSP measured by CNFL. N-3 supplementation could be a targeted nutritional therapy to address small nerve fibre damage in DSP.

Mental Health

The brain requires omega-3s for proper development and function. There is a clear link between omega-3 intake and mood, depression, anxiety and optimal cognitive function. In children with mental health challenges, Auum Sublingual-D was shown to dramatically improve communication, aggression, moodiness/frustration and participation at school.

Sports Performance

Athletes win and lose based on the efficiency of their nerves! All muscle contractions result from nerve signals and therefore superior nerve-muscle interaction determines performance. Researchers at the University of Toronto showed that Auum Sublingual-D increased muscle activation 9% and reduced fatigue by %5 in well-trained athletes.

Cancer Neuropathy

Cancer treatment with chemotherapy causes nerve damage with symptoms of pain, numbness and the loss of sensation. Auum is working with researchers at McGill University Health Centre on a clinical trial investigating the use of Auum Sublingual-D for the treatment of cancer neuropathy.