Specific Omega-3, Omega-6 Polyunsaturated Fatty Acids and γ-Tocopherol in the Therapy of Relapsing Multiple Sclerosis, How and Why: the Paradigm of NEUROASPIS® PLP10 Intervention Efficacy

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Introduction: Multiple sclerosis (MS) treatments are products of reductionism, partially effective with no (re)myelinating/neuroprotective abilities associated with significant side-effects. We aimed to assess whether our novel interventions, formulated based on systems medicine (SM), comprising specific polyunsaturated fatty acids (PUFA) and vitamins reduce disease activity in patients with relapsing remitting (RR) MS who were either treated with disease modifying treatment (DMT) or untreated.
Methods: We contacted a 30-month randomized, double-blind, placebo-controlled, proof-of-concept clinical study at the CING. Of a total of 80 patients, 20 were randomly assigned to receive intervention A (docosahexaenoic acid (DHA)/eicosapentaenoic acid (EPA) (3:1 w/w) omega-3, linoleic acid (LA)/gamma(g)-linolenic acid (GLA) (2:1 w/w) omega-6 fatty acids, omega-3/omega-6 (1:1 w/w), other specific PUFA, monounsaturated fatty acids (MUFA), minor quantity of specific saturated fatty acids (SFA), vitamin A and vitamin E), 20 to receive γ-tocopherol, intervention C, 20 to receive the combination of A and C, intervention B (PLP10) and 20 to receive placebo, as an oral solution, once daily. The primary end point was the annualized relapse rate (ARR) and the key secondary end point was the time to disability progression. The red blood cells (RBC) from each patient blood collection sample at every prescheduled assessment were used as the cells of reference; for evaluation of any correlation between possible efficacy and PUFA profile within the RCB membrane. ISRCTN87818535.
Results: PLP10 reduced the ARR by 70% (p=0.003), in relation to the baseline ARR and the placebo increased by 46% (p=0.354). For the primary end point, PLP10 reduced the ARR by 58% (95% CI 0.10 to 0.79, p=0.016) and for the secondary end point, significantly reduced the risk of sustained progression of disability by 86% over the 2-year period (Hr, 0.11; 95% CI 0.01-0.97, p=0.047) vs. placebo. More patients in the PLP10 group (72%) vs. placebo group (20%) were free from new or enlarging T2-weighted lesions on brain MRI scans over the 2-year study. No adverse events were reported. Interventions A and C showed no significant efficacy. The RBC lipid profile was supportive to the reported PLP10 efficacy by the statistically significant increased quantitative content of the aforementioned PUFA within the RBC membrane as well as by the increased significant release of arachidonic acid (inflammation initiator molecule) from the RBC membrane when γ-tocopherol was present (intervention B); supporting the synergistic theory of all PLP10 ingredients for activity.
Discussion: PLP10 treatment significantly reduced the ARR, and the risk of sustained disability progression without any adverse or significant side effects. This is the first clinical study of SM approach medical nutrient formula that holds strong promise as an effective treatment for RRMS.